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The Letigen case revisited from an issues management perspective

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1. Introduction

“Without proper response, societal expectations of today become the political issues of tomorrow, legislated requirements of the next day, and the litigated penalties the day after that.”(Cammillus and Datta, 1991).

A clear understanding of a company's stakeholders and a strategic approach to handling issues enable a company to prevent an issue turning into full blown crisis. Today companies are in a constant struggle to live up to the expectations of their stakeholders, whether it is shareholders, consumers, special interest groups or government institutions. Sometimes companies fail to perform according to expectations and gaps are created that can develop into a crisis if they are not acted upon in a timely manner. In worst-case scenarios, this can result in a product being withdrawn from the market.

In 2002, Nycomed experienced exactly that. After several months of intense negative media pressure regarding the safety of using their product Letigen, the product was finally banned from the market as the Danish medicines authorities saw no other way than withdrawing the product.

The same forces that created the Letigen issue are part of every day life for most companies today. In order to stay competitive, companies must constantly scan their environments for potential issues and try to close gaps between themselves and their stakeholders. This practice aims to prevent issues turning into crisis.

The Letigen case is textbook example of what happens if companies do not have the necessary focus on their external environment. It also demonstrates the potential for an issue to undermine company performance in terms of its effect on revenue, reputation and legitimacy. Without an external focus, proactive behaviour on issues is difficult and resources will be deployed at fire fighting issues instead of preventing them.

1.1 Focus and problem identification

Strategic Issues Management and stakeholder theory help understand how issues evolve and, in combination with unsupportive stakeholders, why issues turn into crises. These theoretical approaches also show how companies can deal with issues and close gaps between the company

and its external environment before they escalate beyond control and, like in the case of Nycomed, result in a product ban.

Therefore, the aim of this thesis will be examine how strategic issues in the business external environment that could have an impact on the organization can be managed so that issues do not turn into crises. This reasoning has led me to the following problem formulation.

1.2 Problem formulation

The purpose of this thesis is, with point of departure in issues management and stakeholder management theory, to analyse what went wrong and what could have been done differently with regard to Nycomed and the Letigen case.

With regards to the problem formulation, “Wrong” should be perceived as the gap between how Nycomed managed the Letigen case in practice, compared to the theoretical approach to manage issues (presented in chapter 3)

1.3 Delimitation

The primary focus of the thesis when dealing with the above problem formulation will be on the analysis to identify what went wrong. By conducting the analysis according to the selected theoretical framework based on issues management and stakeholder theory, the identification and answer to *what could have been done differently* will lie implicitly in the answer of *what went wrong*? Therefore weight will be put on the first part of the problem formulation.

Furthermore, the selected theoretical framework presents approaches to handling issues and stakeholders on an overall strategic level. The consequence of this will be that both the identification of Nycomed’s strategic approach and any suggestions to a different approach will be on this level. An example of this would be that I will suggest an “offensive” strategy, but do not go into detail on how the “offensive” strategy actually should be carried out.

When analysing and dealing with the Letigen issue, any connections to other broader issues in society in general will not be subject of analysis and will only be commented upon on a superficial level.

Finally, one of the central themes in theoretical framework that will draw upon issues management and stakeholder theory is the *gap* in expectations between the organisation and its stakeholders. When discussing the relation between the company and its stakeholders, I delimit myself from engaging in any discussions on moral claims held by one group or the other, in order to produce an objective representation of the course of events as possible that took place during the Letigen case.

1.4 Reading Guidance

The thesis is divided into four main sections: *introduction, theory, analysis and conclusion*. Chapter 1 gives the introduction to the thesis and outlines the problem formulation and Chapter 2 deals with the methodological approach taken to answer the problem formulation and the considerations and choices taken in the academic work process.

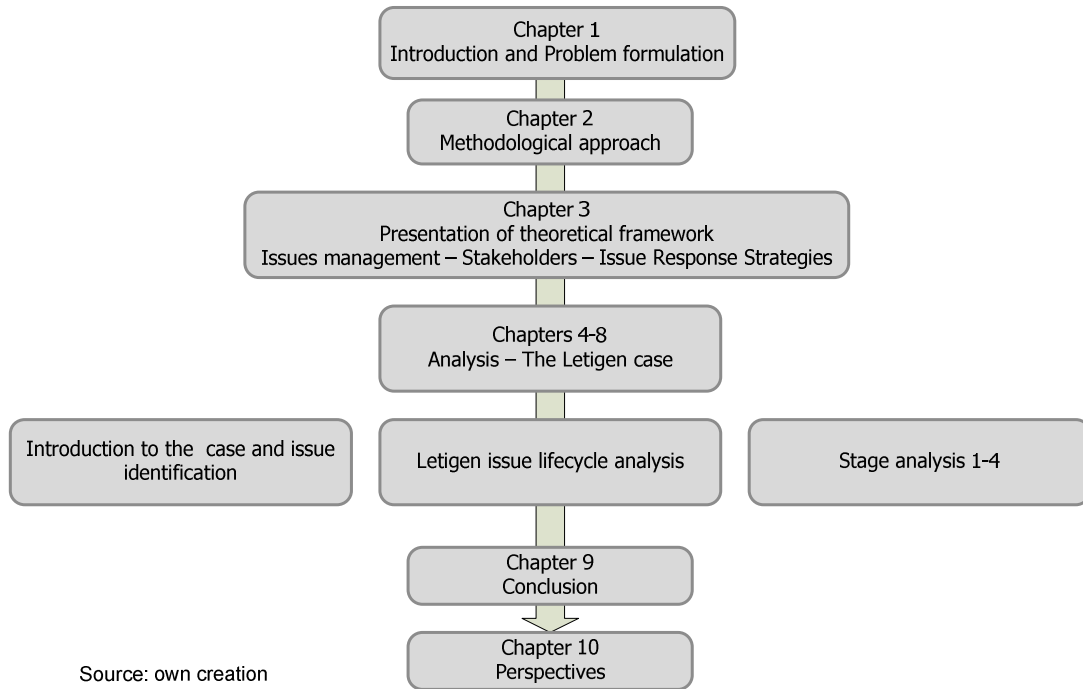
Chapter 3 delivers an introduction to issues management and describes the topics and tools that will be used to build up the theoretical framework. To supplement this, stakeholder theory is included in the framework and the chapter sums up the key concepts from issues management and stakeholder theory that will be used to conduct and structure the case analysis.

In Chapters 4-8, the actual analysis, will be conducted and it will be structured around the issue lifecycle analysis framework. First the analysis will identify the Letigen issue, after which the issue's place in the lifecycle will be determined by conducting the issue lifecycle analysis. Then, in order to answer the problem formulation, the analysis will identify what went wrong and what that could have been done differently in relation to each stage of the Letigen issue lifecycle. This is called the stage analysis.

Chapter 9 presents the conclusion that will answer the problem formulation and sum up the results from the stage analysis. Finally, in Chapter 10, perspectives to the conclusion will be presented.

The structure of the thesis is outlined in the following figure:

Figure 1 – Structure of the thesis



2. Methodological Approach

The following chapter will explain the methodological approach used in answering the problem formulation. The nature of the problem formulation leads to a descriptive-analytical approach to answer the first question, *what went wrong for Nycomed in the Letigen case?* and a normative problem-solving approach to answer the second part of the problem formulation as to *what could have been done differently?*

Thus the purpose of the thesis is two-fold. First, to conduct a historic case study structured around a theoretical framework developed using existing issues management and stakeholder theory, and secondly on based on this framework suggest a different strategic approach to manage the Letigen issue.

2.1 Academic work process

I have chosen to follow a deductive approach by taking the point of departure in existing and acknowledged theory and models. Issues management theory and stakeholder theory provide both useful tools and empirically proven concepts that, when combined, deliver a powerful tool with both analytical and diagnostic capabilities. This choice of theoretical deductive approach enabled identification of which factors were relevant to analyse, when processing the collected data to complete the historic case study and to answer the problem formulation. The development and choice of analytical framework will be explained in section 2.5.

2.2 Methods of data collection

I have chosen to use Heine Andersen (1988) data collections methods to generate the empirical data that will be used to conduct the analysis of the Letigen case. According to Andersen, data can be generated through the following three methods: the documentary, the observing, and the questioning method (Andersen 1988, p.63). In this thesis I have chosen to use the documentary method to collect secondary data and the questioning method to collect primary data through an explorative interview with Nycomed. In the following, it will be described how each method has been used as well as a discussion of the reliability and validity of the sources.

2.2.1 The questioning method – collection of primary data

The primary data collection has been conducted through the completion of a two-hour personal explorative interview with two representatives from Nycomed's communications department. This initial interview provided knowledge on Nycomed's approach to issues management (or lack of) and their view on the Letigen case, i.e. why did the issue emerge and what did Nycomed do to prevent the crisis. The data gained from this interview will be used as a base of reference in relation to the analytical framework when conducting the analysis with the purpose of answering the problem formulation. To get a better insight to how Nycomed saw the evolution of the Letigen case, the interview was conducted in an open and personal style, where the interviewees openly expressed their personal point of views to how the case was handled. Because of the openness in expressing their opinions the two interviewees requested to be anonymous when their opinions are reproduced in the case analysis. The information gathered from this interview is pivotal in analysing the Letigen case as it has provided insight to actual management of the Letigen case.

2.2.1 The Documentary method – collection of secondary data

The documentary method is used as the primary way of collecting/generating data. The majority of the data used in this thesis are secondary data. Apart from the books and journal articles supplying the theoretical framework, the secondary data have been obtained by investigating a variety of information sources including press articles, company documents, online resources and databases, industry publications, and through scanning websites belonging to the involved parties in the Letigen case.

A general advantage of using the documentary method for data generation is the availability and the easy access to a large quantity of data (Andersen 1988, p. 44). A general disadvantage of the documentary method is that it is not possible to control the subjectivity of the data. In some cases the documentary material can be controlled in advance and manipulated towards already made conclusions (Andersen 1988, p. 44-45). As the majority of the empirical data consists of press articles, it is important to have a critical stance to the authors' subjective opinions and motives.

In the theoretical framework that will be used to analyze the Letigen issue, the media plays a key role in the development of the issue, and the number of printed articles and negative content will be used to exemplify the pressure Nycomed's external environment posed during case. In order to do

this, the following method has been used to collect and process media related secondary data.

The national online media database Infomedia was used to conduct the search for press articles. The search was conducted on the words “Letigen” and “Nycomed”, with search dates ranging from January 2002 until January 2003 resulting in 58 articles (originally printed from late June 2002 to January 2003). These articles were printed in the leading Danish newspapers, such as Ekstra Bladet, Berlingske Tidende, Morgenavisen Jyllands-Posten, Politiken, Information and BT. Also a limited number of regional newspapers were represented. A limitation to this approach is that Infomedia at the time did not cover all regional and local newspapers. The Letigen exposure could therefore be larger than presented here. (Please see the list of references for a full overview of the articles)

In the analysis, the media is characterized as one entity or stakeholder and will be labelled “non-supportive” to Nycomed during the Letigen case. This characterization is based on a content analysis conducted when processing the data by focusing on the following factors: headline focus, focus on serious adverse side effects and Letigen, focus on deaths related to Letigen, focus on Nycomed as responsible for the above three. Based on this analysis, it is my subjective assessment that the majority of the articles had content that could either harm Nycomed or Letigen’s performance in terms of sales and reputation. Additionally, processing the articles has been an important source of facts and events that took place during the Letigen case, as well as providing information concerning the development of stakeholder positions relevant for the case. This information is also used to complement facts regarding Nycomed’s position to the issue during the duration of the Letigen case.

In order to use the this data in the analysis and practically relate the media development to the issue development in the issue life cycle, data has been structured along a timeline showing: number of involved media, number alleged adverse side effects related to Letigen, and number of deaths related to Letigen. In addition to using the collected press clipping as background information to identify the course of events that describe how the Letigen developed, the information collected from these press clippings will also be used as primary data in the empirical analysis to identify the Letigen issue lifecycle, the stakeholders involved in the issue and to describe how Nycomed responded to the issue to general public.

2.3 Critique of Data

Although I have argued for a method to deal with data, it still leaves some issues that can be criticized. A basic notion within social sciences and other fields for that matter is the complex situation of subjectivity. The only meaningful way this can be dealt with in the current context is 1) to bear in mind that things are not always what they seem and 2) to continuously provide objective arguments that support current statements, i.e. statements found in the literature or from other sources with empirically tested results. However referring to definitions of objectivity this situation very seldom exists, because an object will always be subject to an observation when presented to us (Andersen, 1994).

2.4 Analytical Framework

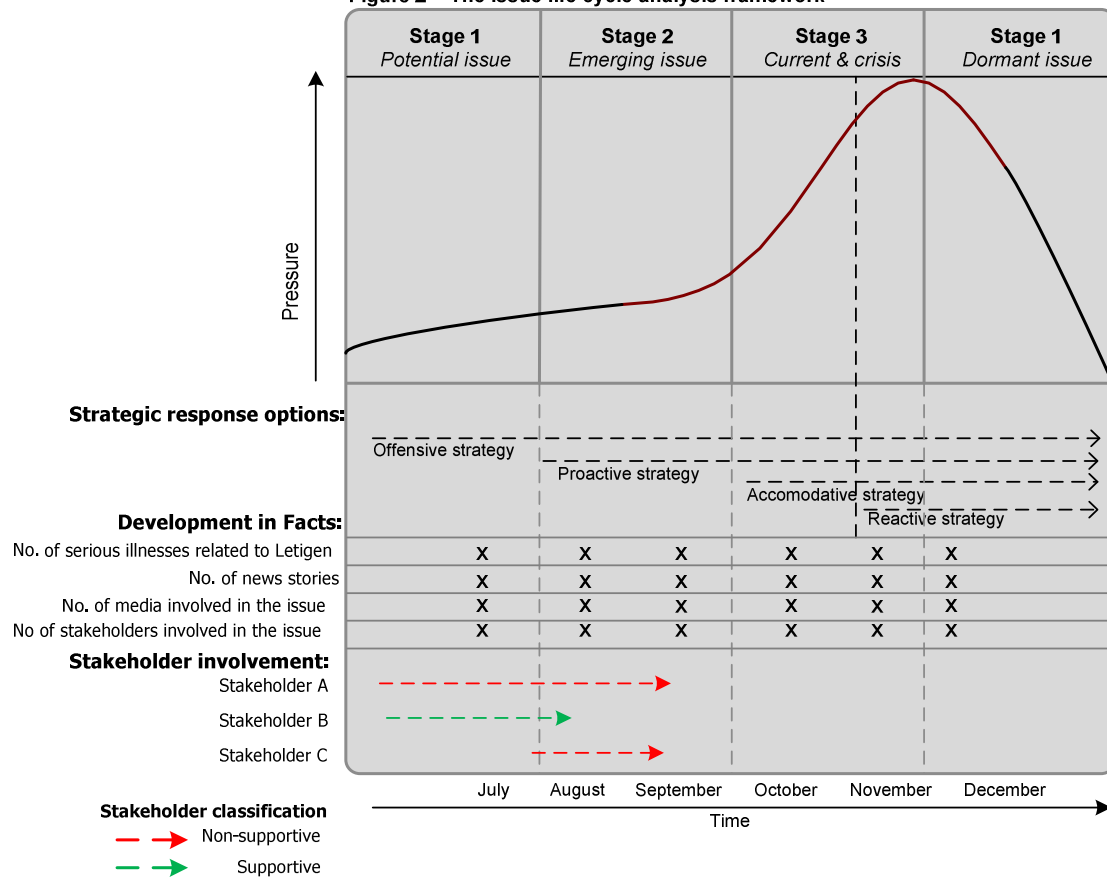
I have developed the following framework presented in figure 1, based on the key concepts from the issues management and stakeholder theory that will be presented in chapter 3. The purpose of the framework is two-fold. First it will structure the case analysis and second it contains the key concepts from issues management and stakeholder theory that can be used to analyse what went wrong in the Letigen case and indicate what could have been done differently.

The framework is build up around the issue lifecycle concept and shows the available strategic response strategies that can be applied at each stage of the lifecycle. As a representation of the pressure Nycomed was subject to during the case, the model also outlines the main components of what the “pressure” consisted of, namely; development of facts, non-supportive stakeholders, media involvement and media coverage. The model is combined with the results from the stakeholder identification process and outlines the involvement from supportive and non-supportive stakeholders, in order to give a clear picture of the company’s bases of support and opposition. During the case analysis, other key concepts of the issues management theory that will be presented in chapter 3 will be included where relevant in the analysis.

As the model is based on key concepts derived from the existing literature on issues and stakeholder management, I will argue that the *theoretical* components of the model are valid and useful to analyse the case at hand. The Letigen lifecycle analysis in section 4.2 will establish the actual lifecycle of the Letigen issue and incorporate that into the model. By comparing the *theoretical*

issue lifecycle concept with the *actual* lifecycle for the Letigen issue, the model is operationalised and will provide a real picture of the issue's development.

Figure 2 - The issue life cycle analysis framework



Source: Own creation

Critique of the framework

The advantages of using the issue lifecycle analysis framework presented in figure 2 are that the model captures and combines the central elements of issues management and stakeholder theory. This framework provides a structure for analysing the Letigen case throughout the full development of the issue through the four stages of the lifecycle. The analysis will be structured around the four stages and build the fundament for answering the problem formulation.

3. Theoretical framework

The purpose of this chapter is to provide and explain the main theoretical elements of issues management theory that will be used develop the theoretical framework that structures the analysis of the Letigen case.

3.1 Issues Management

The term issues management has been around for about three decades and aims to identify assess and deal with threats and opportunities in the external environment. Issues management is the product of a reaction towards the turbulence and criticism that impact business. In a world characterized by constant change, every company needs a system to provide early warnings of emerging business, social, political and economic issues that could threaten corporate performance. As a discipline, issues management focus on how to avoid issues turning into crisis situations.

3.2 Defining issues management

Issues management is defined as “developing a systematic process by which the company can identify, evaluate and respond to strategic issues affecting the company (Ansoff, 1980:131). The main concept of issues management is to uncover issues that may play an influential role in the relationship between an organisation and its stakeholders (Winter & Steger 1998:29), with the underlying notion that companies should, as early as possible, identify which of the trends and issues that has the potential to reach the public agenda.

Chase and Jones defined issues management as a process companies can use to identify, analyze and manage emerging issues and respond to them *before* they become public knowledge. (Chase and Jones in Regester & Larkin 1998:38). In that sense, issues management involves looking into the future to identify potential trends and events that *may* influence the way an organization is able to operate, but that currently *may* have little real focus and urgency. The process of dealing with external issues should also be seen as an integral part of strategic management. The rationale for an increased strategic awareness to external factors is that due to a constant changing environment, where new issues emerge, develop, and disappear on an ongoing basis that could affect organizations negatively, companies should adapt an *outside-in* thinking of the environment, By understanding the external changes and developments in their external environment, companies

will have a better chance of future survival (Regester & Larkin, 1998:23). Combining Regester & Larkin's external focus with Ansoff's definition provides the working definition of issues management that I have chosen to use in this thesis:

"Issues management is the systematic process by which companies can identify, evaluate and respond to strategic issues affecting the company in their external environment"

The following part will go through the issues management process model that is the tool used to identify trends in companies (or organizations) external environment.

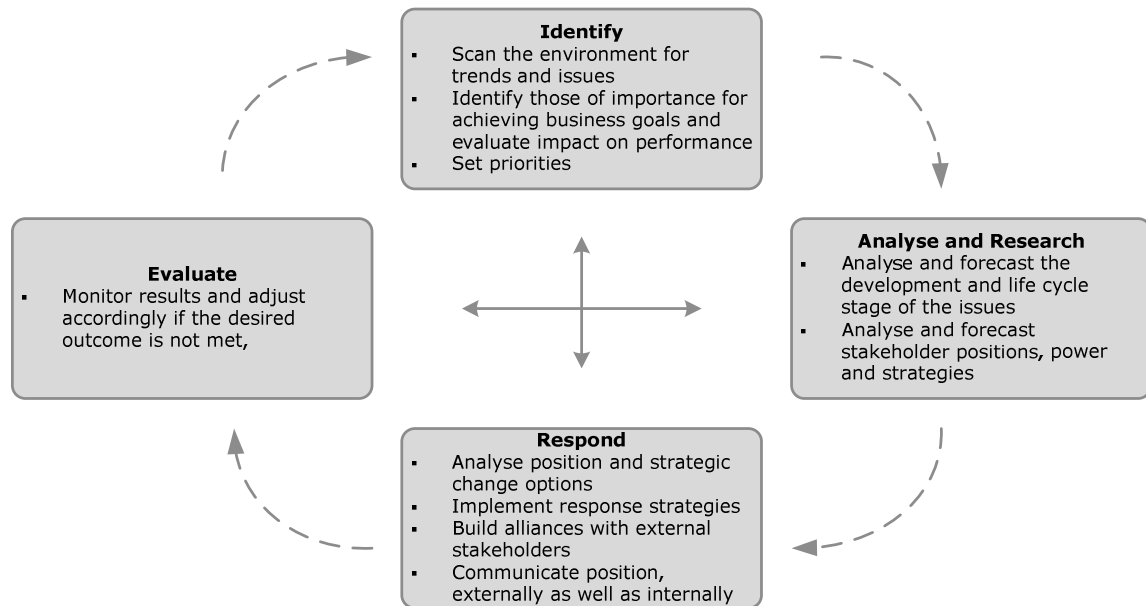
3.3 The issues management process model

The basic notion of issues management is that it is a strategic tool used to forecast future external possibilities and threats to the organization by scanning its environment. Environmental scanning is not new and revolutionizing to the strategy formation process. Companies still use PEST and SWOT analyses, to identify external factors that could affect the company and to decide future actions. Unless conducted on an ongoing basis, these analyses tends to be static and only deliver a momentary picture of a company's external environment. The strength of issues management process is that its conducted as a continuous process that involves all businesses and functional units (Heath 1997:24).

The way companies respond to emerging external issues takes many forms. If issues are not anticipated and identified early in their development, the response will be re-active and crisis management oriented (Heath 1997:24). Another response to emerging issues is to build a capability to anticipate potential future crises and thereby steer away from them.

The issues management process consists of several interlocked stages. The model outlined in figure 3 suggests four stages. Depending on the author, issues management process models vary in stages and labels but they basically describe the same process. In this dissertation, the issues management process model is based upon Heath (1997:90), Gaunt and Ollenburger (1993:P207), Winter & Steger (1998:c3), Palese and Crane's (2002:288) and Chase (1984:36). I have chosen an approach to the issues management process that consists of four main steps, 1) *Issue identification*, 2) *Issue analysis*, 3) *Strategic Response* and 4) *Evaluation*. The process is outlined below.

Figure 3 - The issues management process model



Source: own creation based on Heath (1997:90), Gaunt and Ollenburger (1993:P207), Winter & Steger (1998:c3) and Palese and Crane (2002:288)

Having outlined the main the parts of the issues management process, the following sections deal with the different elements theoretically. Some elements are obvious and common sense (e.g. evaluation) and some are interlocked, e.g. sections regarding issues identification and analysis. Therefore the model is discussed by emphasising the theoretical topics around the following three clusters:

1. Defining an issue and its nature throughout the issues life cycle
2. Stakeholder analysis
3. Issue response strategies

3.4 Defining issues

The simple definition of an issue is that it represents ‘a gap between corporate practice and stakeholder expectations’. Wartick and Mahon (1994) have contributed with a more specific definition. According to their framework, issues can be explained by three overall themes; impact, controversy and expectational gap.

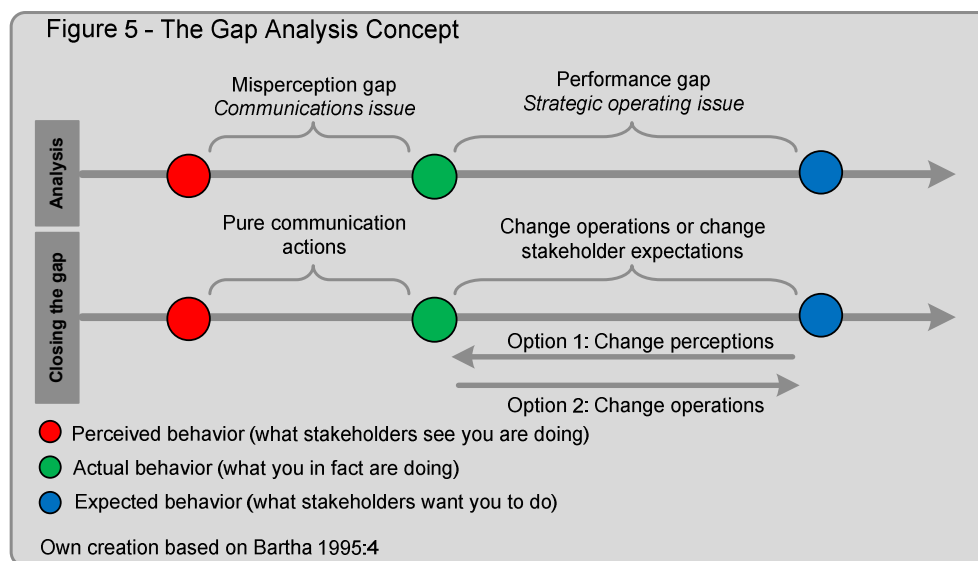
The **impact theme** concerns the impact that changes in the external environment will have on the company. The basic notion here is that an issue is the result of “*major environmental trends and possible events that may have major and discontinuous impact on the firm...or a trend or condition, internal or external, that, would have significant effect on how a company is operated over the period of its business plan*” (Wartick & Mahon, 1994:295). This theme suggests that an issue hold three dimensions: a) the firm specific nature of issues, b) the importance of the future as well as the present, and c) both internal and external change as possible sources of issues. Furthermore, in order for an issue to exist, possible change must have potential to affect the organization. If change occurs, for instance as a demographic trend or a catastrophic event, but the organization is not significantly affected, then no issue exist.

The **controversy theme** implies that, in order for an issue to exist, there must be a conflict between two or more identifiable stakeholder groups. The topic of the conflict is how the company is allocating its resources to address a particular concern. Contestability among stakeholders is the key dimension of change in relation to the emergence of a corporate issue. The change that happens should be understood in terms of changes in stakeholder attitudes and perceptions relating to the natural environment, product safety, employee policies, or any other area of corporate performance. As new stakeholders are inserted into the corporate context, conflict may result among the legitimate demands of these varied but important groups (Wartick & Mahon, 1994:296).

The last theme from which a corporate issue can be defined is **the expectational gaps** theme, and will be used as the working definition of an issue in this dissertation. Defining an issue according to this theme is identical to the classic management/control problem of trying to match actual and desired performance. The expectational gap definition explicitly includes a concern about impact and it implies controversy (Wartick & Mahon, 1994:297). Under this theme, an issue is defined as “*a gap between social perceptions of business behaviour or performance and social expectations about what that performance should be.*” (Wartick & Mahon, 1994:298).

Wartick and Mahon’s definition of corporate issues is very useful and easy to conceptualize, when combined with the gap-analysis concept developed by Bartha (1995:pp1,8). The principles of the model are outlined in figure 5 below.

Bartha (1995:pp.1-5) has identified two types of gaps that require different solutions. The misperception gap, which represents an issue that can be eliminated through pure communications actions. This means that a company just has to tell what it actually does and the aim of this so that stakeholders adapt their current perception to the facts stated by the company. The performance gap is the difference between the way the company actually performs and the expectations of its stakeholders. This represents the basic strategic problem for companies in issues management – how to close the gap. Thus issues management is about strategic decision-making. This will be dealt with further in section 3.7 - Issue response strategies.



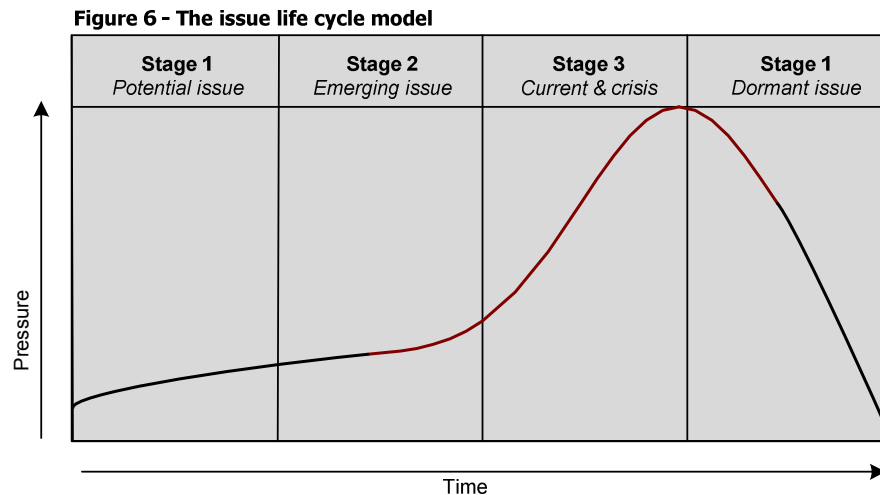
For the purpose of discussing the term issue and its nature, the above model is useful to keep in mind. Issues only emerge when a gap between what the company does and what stakeholders expect it to do is present. Thus the aim of issues management is to close gaps before they widen and develop to a degree where issues will turn into crisis. In this way, managing issues should not be considered a defensive activity. In addition to minimizing risks associated with change, positive opportunities for repositioning a product or process, or communicating new benefits may exist if they are looked for. The creation of issues, or the gathering and management of information and opinion relating to an issue, can be harnessed by an organization for significant competitive or social advantage.

3.5 The Issue Lifecycle concept

An issue originates as an idea that has potential impact on some organization or public and may result in action that brings about increased awareness and/or reaction on the part of other

organizations or publics. This process can be described as a cycle made up of four stages: 1) Potential 2) Emerging, 3) Current & Crisis and 4) Dormant (Regester and Larkin, 1998:48). In Figure 6 below, the vertical axis of the diagram represents the level of pressure exerted on an organization by a developing issue and the horizontal axis represents the various stages of development. At each stage of evolution pressure mounts on the organization to respond because of the increasing importance of the issue.

The basic premise for the issue lifecycle is that issues tend to develop in an evolutionary pattern going through the four stages described above (Gaunt and Ollenburger, 1993:205). Though there has been different approaches to the lifecycle model (Gaunt and Ollenburger, 1993:205, Pratt and Herrero, 1995:27, Regester & Larkin, 1998:48), the results that it delivers are basically the same; an issue (normally) begins very slowly in its early stages (*Potential* and *emergent* issues), then the issue takes form and develops into the *current* stage, typically in terms of extensive public focus and awareness, and finally, the issue peaks in its maturity (e.g. in the form of a crisis), and after that it dies in terms of lack of public focus and awareness (*Dormant* stage) .



Source: Own creation based on Regester & Larkin 1998:48

The development described above is closely related to the ‘expectations gap’ mentioned earlier. Issues initially arise when a gap develops between what the company does and what its stakeholders expect it to do (e.g. in terms of performance, environmental concern, product quality etc.). The first stage might last months or years, as the public first develops an expectation of a problem with the way a company’s does things and that then develops an expectation to the company that they should change their practices. As the issue moves to the second stage,

concerned stakeholders will try to generate public interest in the issues and try to politicize the issue, advertising for regulatory action. The next two stages mark the movement of the issue into the governmental arena and the risk for regulation. (Hainthsworth in Gaunt and Ollenburger, 1993:206)

While the model assumes that an issue moves sequentially through these four stages, companies need to take actions early in the lifecycle to effectively stop its further development. (Camillus and Datta, 1991:68). Early action and response to an issue may help the company resolve the problem. If a company fails to respond to an issue in its early stage, the company will lose considerable decision-making discretion as legislation is crafted and regulations enforced upon those involved (Gaunt & Ollenburger 1993:206).

3.5.1 Identifying the issue's place in the lifecycle

The application of the basic lifecycle model is relevant when analysing issues and planning strategic responses, as the available strategic response options depend on where the issue is positioned in the lifecycle (Heath 1997: 96; Renfro 1993: 30; Gaunt and Ollenburger 1993:205, Regester and Larkin, 1998:47). The fundamental relationship in any issues life cycle is changing public attention or pressure over time. A clear weakness of the issues management theory is the lack of measurement methods that can be used to measure the degree of pressure an organization is subject to in order to place the issue in the lifecycle. Winter & Steger has developed a method to identify public awareness, which in their definition is very close to the "pressure" definition in the basic lifecycle model (1998: 60). By assembling experiences from a large amount of firms practising issues management, Winter & Steger (Ibid) found that public awareness can be seen as an aggregation of different factors depending on the issue, exemplified by the following four factors:

1. Number of events (events triggering outside pressure)
2. Number of readers/receivers (expansion of an outside pressure issue in the public)
3. Level of importance (development of topics)
4. Number of countries (stakeholder awareness in an international context).

By counting events, media coverage, topics, stakeholders etc. the growth of an issue can be measured over time and can be graphically expressed by converting the results into diffusion curves. By multiplying the factors into one model, showing public awareness on the Y- axis and

time on the X-axis it is possible to identify the lifecycle for an issue (Winter & Steger, 1998:61). Having presented how issues are identified in terms of their place in the lifecycle, the following will examine the characteristics of each stage.

Stage 1 – Potential issue

An issue arises when an organization or group attaches significance to a perceived problem (or opportunity) that is a consequence of a developing political/regulatory or economic or social trend (Regeister & Larkin, 1998:49). It begins to gain definition when an organization or group plans to do something that has a consequence for another organization or group, thereby creating the seed for a future conflict. In Figure 6 the early *potential* stage is a defined condition or event that has the potential to develop into something of importance. Issues which exist in this phase have not yet captured significant expert or public attention, although some specialist will begin to be aware of them (Regeister & Larkin, 1998:49).

At this stage, the issue often lacks sufficient form or substance to justify deliberate external intervention. Issues that make it past stage 1 are alive, have a momentum of their own and are capable of being modified as they move towards resolution (Regeister and Larkin 1998:50). In this stage, groups or individuals generally begin to establish a certain level of credibility in areas of concern and seek out support from other influencers and opinion leaders who are involved to some degree in that particular area of interest. Thus the main question is what are the factors that allow an issue to continue through the lifecycle? Winter and Steger's have developed an issue checklist, consists of eight questions that can be used to forecast an issue's potential for further development: (Winter and Steger, 1998:34)

1. Are the arguments against the issue plausible?
2. Does the issue evoke emotions? Is it understandable – visual, touching – by the public?
3. Is the issue media-friendly?
4. Are there connections to other issues of the company or other companies?
5. How strong is the key stakeholder?
6. How isolated is the company?
7. How far have the dynamics of the issue all ready evolved?
8. How easy is the solution?

The prioritisation process is crucial as no organisation can address all issues and therefore the purpose of Winter & Steger's exercise is to limit the number of issues that should receive

management attention, by only focusing on those that has the potential to influence the well being of the company.

Stage 2 - Mediation and amplification: emerging issue

As groups emerge, and lines become drawn, a process of mediation and amplification occurs among other individuals and groups who may have a similar viewpoint and may be expected to react in a similar way. The emerging issue stage indicates a gradual increase in the level of pressure on the organization to accept the issue, in most cases this increase is the result of activities by one or more stakeholder groups as they try to push or legitimize the issue. Put in another way, the issue is no longer a matter for a confined group, e.g. scientists, a special interest group or other persons or groups – in this stage the issue is about to be spread out to the public arena and here, the media play a key role. (Regester and Larkin 1998:50,51). The emerging stage is critical and has the effect of accelerating the full development of the issue. It is therefore essential that companies which are targeted conduct regular and effective monitoring of the commercial, regulatory and social environment in order to identify stage 2 issues and begin to formulate action plans to deal with them.

Stage 3 – Organization: current and crisis issue

When an issue reaches stage 3 in its lifecycle, groups begin to seek a resolution to the conflict that is either acceptable to their best interests or at least minimizes potential damage. In the *current* phase (stage 3), the issue has matured and is displaying its full potential upon those involved. It is now very difficult to affect the issue as it has now become enduring, pervasive and increasing in intensity. As seen in Figure 6 there is very short time to react before the issue ramps up from the current to the crisis phase. Once an issue has reached its peak or crisis status, formal institutions may become involved (such as regulatory authorities), there may be full blown negative media coverage, consumer boycotts etc. At this point a company may suffer reputational damage and may become unnecessarily restrained by regulatory action that could affect the profitability of the company (Regester and Larkin 1998:pp52,53)

Stage 4 – Resolution: Dormant issue

Once an issue receives the attention of public policy officials and enters the policy process, either through changes to legislation or regulation, efforts to resolve the conflict become costly. Once an

issue has run its full course through the lifecycle it will reach a height of pressure that forces an organization to accept it unconditionally. When the issue has reached the dormant phase it does not necessarily mean that the issue is 'dead'. If it is resolved it has the possibility to come back to life at a later point in time with the possibility of bringing an organization back into the limelight (Regester and Larkin 1998:54).

3.5.2 Limitations to the lifecycle approach

The lifecycle approach describes the linear and sequential path of a single issue through the lifecycle. As mentioned earlier, issues do not necessarily follow this but, instead, follow paths that reflect the intensity and diversity of the values and interests that stakeholders bring to an issue, i.e. an issue can be disturbed in its path in different ways that will cause it to break from the normal evolutionary path. The reason to why an issue might deviate from the sequential evolution described in the lifecycle model and cause issues disturbances can, according to Bigelow et al. (1993:21), be found in a number of forces outside the control of any organization or stakeholder. Some of these forces are described below. (The following part is based on Bigelow et al, 1993:pp21-26)

Facts disturbance

Facts related to issues include changing demographics, economic or political trends, technological breakthroughs, crises, events or statements by public officials. These facts serve as early warning signals that an issue might emerge. However, facts might also arise in the course of an issue's evolution, causing it either to diffuse or increase in intensity. It can also cause disturbances such as jumping, speeding up or other of the disturbances outlined above. Facts in themselves are neutral. However, the meanings different stakeholders ascribe to them are not. Therefore, it is not simply facts but the meanings ascribed to them that affect an issue's evolution.

An issue's evolution can be affected by facts in two distinct ways. First, they may diffuse an issue that has already become public by recasting it. Second, crises in particular serve to galvanize public opinion, and catapult an issue into the public agenda, before all stakeholders have interpreted it and taken positions, thereby skipping stages and being resolved by direct regulatory action.

Stakeholder disturbance

Most of the issues lifecycle models assume that issues follow a linear sequential path through the lifecycle. The assumption in the model is that all stakeholders are at the same *stage* in an issue's lifecycle at the *same* time. In effect, issues are treated as something that stakeholders may be able to influence through their actions but which essentially exist independently of stakeholder involvement. However some stakeholders might be informed and engaged in strategies before others become aware of the issue. Just as facts can catapult an issue to the forefront of the public agenda, so can stakeholders for instance by champions who may push issues forward, thereby skipping stages.

Issues competition disturbance

Some issues may be discussed in isolation from other issues. At any given time multiple public issues are at various stages in their evolution, competing for attention not only on public agendas but on organizational ones as well. The emergence of new issues may abort or stall the development of existing issues or recast existing ones.

Scope disturbance

An assumption of the issues lifecycle model is that issues can be resolved. The scope of an issue is assumed to be relatively well bounded, clearly defined, and thus capable of resolution. There are examples though of issues that have evaded resolution. As new values and expectations grow the issue restarts every time the issue reaches the dormant stage.

The issue lifecycle model can still be useful to understand the development of an issue and define possible strategies to deal with it according to its position in the lifecycle. The forces described above that can affect the evolution of an issue just stress the need for companies to be scanning the environment and be prepared to act proactively and reactively to issues that could affect the company.

3.6 Analysing stakeholders

In order to understand the risks or opportunities an issue can imply to a company, it is not sufficient only to analyze the issue itself in terms of the issues lifecycle, as outlined in the previous chapter, but key stakeholders' influence and stance on an issue also has to be taken into

consideration. In order to effectively deal with stakeholders and develop issue response strategies that will close eventual gaps, the identification of those stakeholders that are involved or might become involved is crucial.

According to Freeman (In Winter & Steger 1998:9) a stakeholder is an individual or group that can affect or be affected by the accomplishment of an organizational goal because each has a “stake” in the company. Freeman’s definition is important because it underlines a two-way interaction perspective, between the firm and its stakeholders (the effect is two-way), but it also defines stakeholders very broadly, making it possible for almost anyone to become a stakeholder.

Mitchell, Angle and Wood (1997:pp.865,869) have developed a more dynamic stakeholder model in which stakeholder classes can be identified on the basis of a combination of three attributes:

- The *legitimacy* of the group’s standing as a stakeholder or of its claim on the firm
- The *power* of the stakeholder to influence behaviour
- The *urgency* of the stakeholder’s claim.

Stakeholders that possess all three attributes are core stakeholders and the more they express each attribute, the more attention should be paid to them. This means that some stakeholders are more important to the company than others because they have a greater possibility to influence public debate. Another important aspect to this framework is that stakeholders cannot be labelled permanently into one category, but they can change stakeholder class over time, depending on their interest to an issue for the organization. Furthermore, stakeholders have interrelations which mean that some stakeholder groups might collaborate and create alliances, thereby possibly having a greater impact on the company if controversy arises. This framework is very useful in the issues management process when prioritizing between issues, as Mitchell, Angle and Wood also state that a company cannot be everything to everybody – their approach has to be strategic (Ibid:872).

Winter & Steger has also contributed the understanding of stakeholders in an issues management perspective. Many companies, according to these authors, focus only on a narrow set of stakeholders such as shareholders, employees and customers. While these issues are important to companies, most issues do not arise in that context but in other stakeholder relations. In order to better understand the stakeholder environment from an issues management perspective, Winter &

Steger divide stakeholders into the *transactional environment* and the *contextual environment*. (Winter and Steger, 1998:11). Stakeholders in the transactional environment can influence companies through direct business relations while groups that belong to the contextual environment have no direct market or business relations with companies and use other means of influence. The two dimensions are shown below in figure 7 (Winter and Steger, 1998:12).

Figure 7 – Possible demands from stakeholder groups and their sources of power

Transactional environment			Contextual environment		
Group	Possible demands	Possible pressure tactics	Group	Possible demands	Possible pressure tactics
Customers	Product quality, service value	- Purchasing decisions			
Employees	Security, compensation, job satisfaction	- Departure from company - Negative publicity - Reduced performance	Governments	Taxes, employment, environmental protection	- Legislation - Legal fines
Suppliers	Regular payments, continuity of business	- Refusal to meet orders - Supplying to competitors	Media	Fair information	- Bad publicity
Shareholders	Dividends, capital growth, safe investment	- Voting and inspection rights - Buying and selling			
Creditors	Interest, security of capital	- Refusing loans and calling in loans	Social activist groups	Employment, no discrimination, social justice	- Publicising issues - Lobbying governments - Influencing consumers
Insurances	Safe operations, safe products	- Refusing insurance coverage and cancelling contracts	Environmental activist groups	Preservation of the environment	- Publicising issues - Lobbying governments - Influencing consumers
			Consumer organisations	Product quality, environmental protection	- Publicising issues - Lobbying governments - Influencing consumers

Source: adapted from Winter & Steger 1998:12

Consequently, Winter and Steger's stakeholder approach adds value to the issues management framework with the knowledge that obvious partners, like customers and shareholders, do not raise issues alone. Company performance also depends upon other stakeholders in society like governments and interest groups.

3.6.1 Stakeholder mapping process

In the process of defining and mapping stakeholders, it should be kept in mind, that the mapping process is perceptual, i.e. any stakeholder group is only as important as perceived by managers or those people in charge of the process. The first step in the process is stakeholder identification. Conceptually this seems like an easy task, but when it comes to practical terms it can be more difficult to ensure the segmentation and identification of stakeholders is conducted properly. In relation to the issues management framework, it is crucial when planning the appropriate response strategies that the identification and segmentation in the stakeholder mapping process catches all

those stakeholders relevant to an issue. In this context, Winter and Steger's *Activist Issue Checklist* shown in figure 8 provides some useful questions to ask when identifying key stakeholders to an issue who are or might become involved in an issue..

Figure 8 - Activist Issue Checklist

- The issue should have a clear aim or goal.
- The issue should be easily understood by the public.
- The issue has a high symbolic value.
- The issue has the potential to damage the image of the company.
- The opponent is strong enough (no "underdog" effect).
- The issue can be packaged in a campaign in which the public can get involved.
- There are solutions that are confrontational, not gradual
- There could be a dramatic element to the campaign to engage the media.

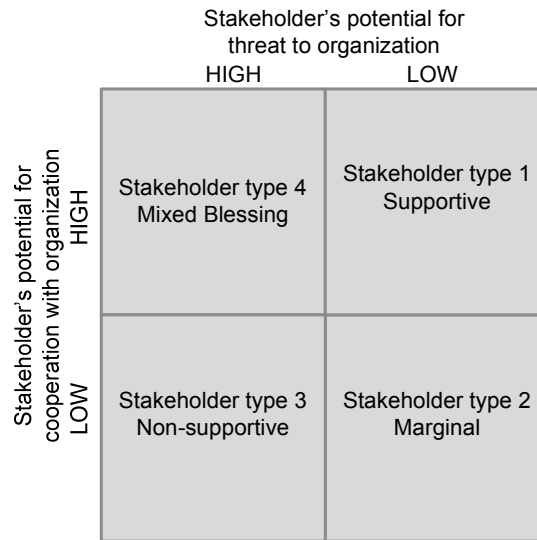
Source: Winter & Steger 1998:83

The limitation to the Mitchell, Agle and Wood's and Winter and Steger's stakeholder frameworks is that they do not outline specific strategies for dealing with the different stakeholder classes in terms of issue resolution. Savage, Grant, Whitehead and Blair (1991) have developed a similar framework for stakeholder identification and outline four generic strategies to deal with the company's stakeholders. The specific strategies will be described in the following chapter. Their framework basically divides stakeholders into four classes according to their potential for cooperation with an organisation and their potential for threat for an organisation. Their framework is outlined in figure 9 below.

Type 1 – The Supportive stakeholder

This stakeholder type is low on potential threat and high on potential for cooperation. The company's internal stakeholders are mostly supportive and externally, suppliers and service providers are usually supportive for the company.

Figure 9 - Diagnostic typology of organizational stakeholders



Adapted from: Savage, Nix, Whitehead and Blair, 1991

Type 2 – The Marginal Stakeholder

Marginal stakeholders are those stakeholders who are not interested in the issue, but with the potential to get involved in a later stage. Normally, they are neither threatening nor cooperative to the company. This stakeholder type potentially has a stake in the company and its decisions, but is generally not concerned with most issues. These stakeholders include grassroots movements, consumer interest groups, and stockholders. Marginal stakeholders usually get triggered by issues such as product safety, environmental issues etc. which could cause either threat or cooperation to increase, for instance by changing into non-supportive stakeholders.

Type 3 – The Non-supportive Stakeholder

Non-supportive stakeholders are those stakeholders who are either not interested in the issue or have a negative stance toward the organization in relation to the issue. These stakeholders have a high potential for threat and a low potential for cooperation, and are often the most distressing for a company. Typical non-supportive stakeholders are: competing organizations, employee unions, government and authorities, occasionally the news media. Activist and special interest groups also fall into this category if they are involved in an issue with opposing views vis-à-vis that of the organisation

Type 4 – The Mixed-Blessing Stakeholder

This type of stakeholder can be compared to the key stakeholder in Mitchell, Angle and Wood's framework. Stakeholders in this category have a potential for threat to the organization as well as a high potential for cooperation. These stakeholders have the power to influence the organization positively but in times of crisis, also negatively. Mixed-Blessing stakeholders are generally short-supply employees, customers and business partners.

In this section, the stakeholder theory and framework has been outlined. The rest of the stakeholder theory is about strategic choice, i.e. how companies should respond to various stakeholders. As mentioned, above this depends on the specific stakeholder and their ability to influence an issue and thereby, implicitly, an organisation. On the more broad level, the issue itself and especially the stage in the issue lifecycle is crucial when deciding an appropriate strategy.

3.7 Developing issue response strategies

“How issues are handled can mean the difference between a crisis out of control and a proactive solution – between profit and loss” (Regester & Larkin 1998:36)

The next step in the issues management framework is to develop strategies to deal with the pressing issues at hand. Chase and Jones have identified three “Issue change strategy options”, labelled the dynamic, adaptive and reactive responses (Gaunt and Ollenburger 1995:207). In their framework, the strategic approaches were structured in relation to the issue and its position in the issue lifecycle model. They reason that if an issue is detected early in the stage of its lifecycle, the organization has the possibility of adopting a dynamic response strategy (proactive) and if the issue is detected late in its lifecycle, strategic options are limited to a defensive response.

The *dynamic response strategy* implies that the company can respond proactively and has the opportunity to influence and shape the issue from its beginning. This strategy should be used when the issue is still in stage 1 or 2 in the lifecycle. The dynamic response implies that the company has developed some kinds of mechanism with which it can track and anticipate changes in its external environment.

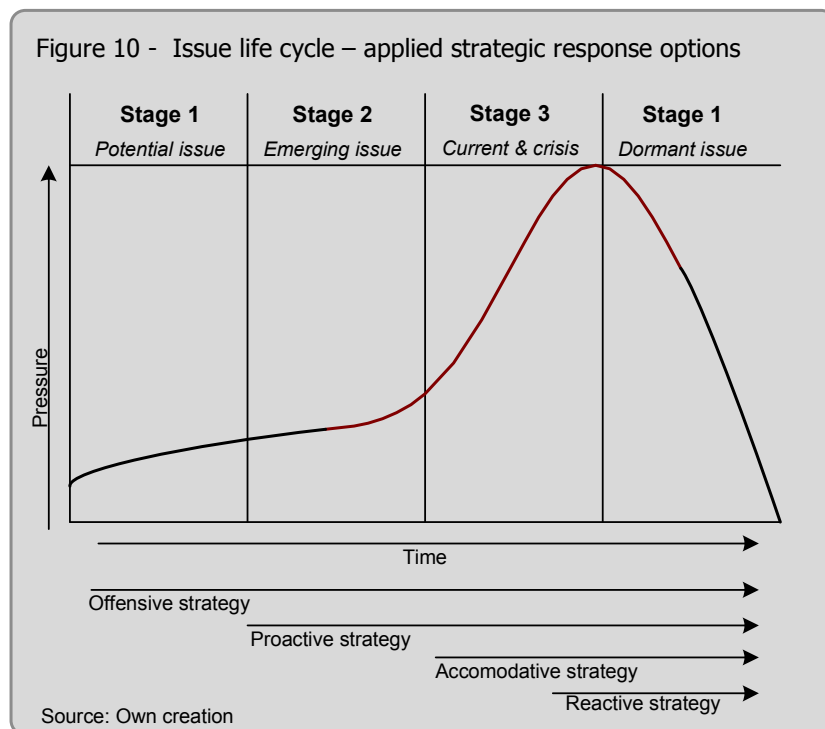
The *adaptive response strategy* means that the company has not acted on the issue at stage 1 or 2, but instead it adapts to the changing public environment. Using this strategy, the company remains inactive or passive until the issue reaches the current stage in the issue lifecycle (stage 3), and then adjust its activities to avoid crisis. This strategic option is defensive in nature as opposed to the dynamic response that can be labelled more offensive.

The last strategic response in Chase and Jones’ framework is the *reactive response strategy*. Here the company remains inactive until the issue reaches the crisis stage in the lifecycle, and then chooses a reactive response to fight against any regulation or legislation posed by authorities to resolve the issue.

Supplementary to Chase and Jones’ model, Buchholz, Evans and Wagley have developed a fourth strategic response strategy labelled the *interactive response strategy* (Buchholz, Evans & Wagley’s 1989: 65). This option, just like the dynamic response, should be conducted in the beginning of the

lifecycle, i.e. stage 1 in order to be able to influence and shape the issue, already before it has become an issue.

On the basis of these frameworks a four-step strategic response model is developed below, summarizing the available strategic options vis-à-vis the position of the issue in its lifecycle. The four strategic options are outlined below and shown in relation to the issue lifecycle model in figure 10.



Offensive Strategy

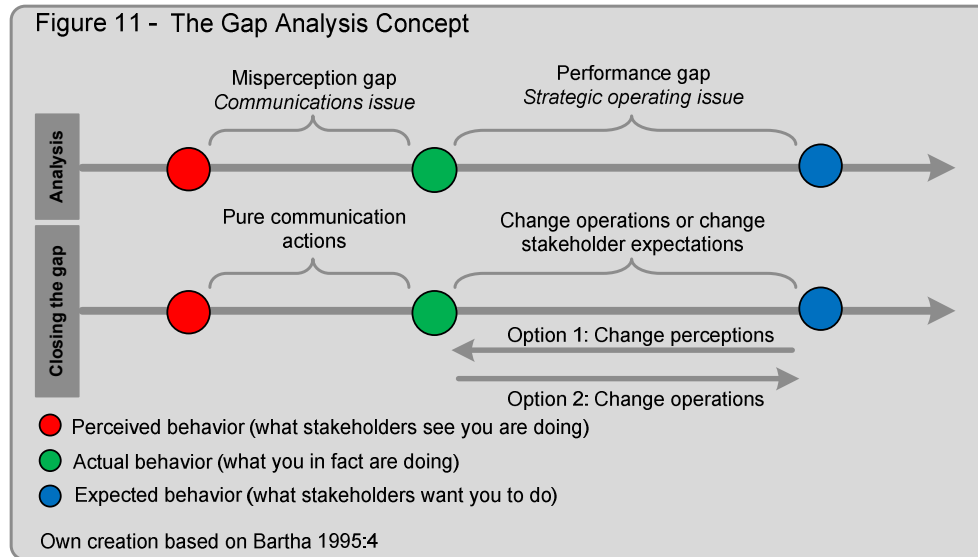
If an issue is detected at an early stage in its lifecycle it can choose to engage in an *offensive strategy*. By doing so, the company recognizes that it has the potential to shape the future development of an issue and by coping with the issue in a timely fashion, even what was perceived as threats to the company can be turned into opportunities. Companies that engage in offensive strategies, also recognize that stakeholders have expectations that must be attended to in order to avoid issues turning into crisis situations.

Should the company choose to use an offensive strategy to cope with an emerging issue, the following conditions are at work:

- The issue is identified in stage 1 or 2 in the lifecycle

- The company recognizes that a gap between corporate performance and public expectations exists.

Then the company decides what closing-the-gap strategy should be used, cf. Gap Analysis framework, to close the expectations gap.



The company can basically engage in three different strategies in order to close the expectations gap. First, the company can engage in symbolic actions, i.e. try to manage stakeholder expectations (and perceptions) through communication actions in order to avoid adjusting or changing the processes that started the gap. Second it can take substantive actions which mean that the company adjusts its organization and business processes and aligns it with stakeholder expectations, so that performance equals perception. Finally, a combination of the two first options could be used. (Bartha 1995:4)

Proactive Strategy

The use of proactive issues response strategies imply that the company already has identified possible external change that will occur and try to position the company according to that change before it occurs. In order to be successful with proactive strategies the companies need to develop anticipatory mechanisms which enable the company to identify issues that will have an impact on the company at an early stage in the lifecycle.

The aim of the proactive strategy is to prevent changes or at least try to minimize the impact and consequences of an event outside the company's control. In terms of the gap analysis framework, the company can use symbolic actions (communications) to manage stakeholder expectations and perceptions so that the current operational framework of the company does not have to be changed. The underlying notion of this strategy is that the company should not take action later than stage 2 in the issue lifecycle, and that the company tries to influence the further development of the issues by influencing stakeholder perceptions. The proactive strategy is somewhat similar to the offensive strategy. Here the company will only be proactive so far that it does not interfere with the company's current business strategy.

Accommodative Strategy

This strategy is the most passive issue response strategy of the four outlined options. Companies taking the accommodative approach simply adapt to the changes brought around by an issue and then get on with their business.

The basic notion of this response strategy is that the company takes a passive approach to any changes and adjusts its organization accordingly. It makes no attempts to influence or fight any new imposed regulation or change. In relation to the gap analysis framework, the company actually changes its performance to close the gap. This is usually done because any stakeholder claims imposed on the organization are considered as legitimate. This strategy is typically adopted when the issue has become current in stage 3 of the issue lifecycle. Taken an accommodative approach to solving the issue at hand gives the company resolution to the problem, but does nothing more than just live up to its stakeholders' expectations.

Reactive Strategy

Companies that choose reactive response strategies basically do not address issues until they reach the crisis stage in the issue lifecycle (stage 3), this implies that a response is triggered by external forces or demands on the company. At this point it is unavoidable that the issue will have some impact on the organization and legislation and regulation from relevant authorities are most likely to occur.

Companies that use reactive response strategies do not treat issues as within their domain of concern, and therefore reactive responses often are defensive in nature, characterized more by fire fighting than prevention. Most likely reactive response strategies will contain efforts to fight the issue in order to oppose or postpone regulatory actions or other imposed actions. Using reactive strategies often signifies that it is too late to have any influence on the resolution of an issue. Unlike the accommodative strategy where the company reacts to the changes made by external forces, companies using reactive response strategies put up a fight.

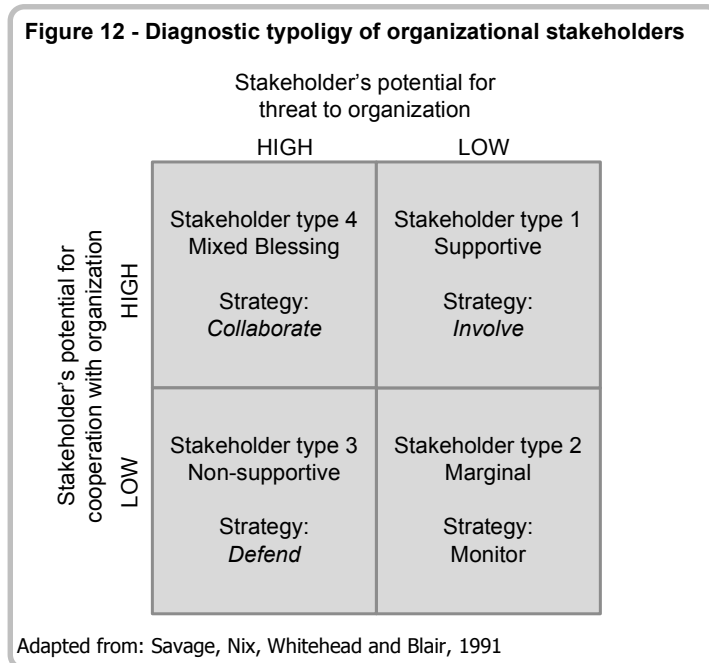
In sum, having defined the issue according to the gap analysis framework and identified the issue's place in the lifecycle, this framework provides four generic strategies that can be used in order to close gaps when they are identified. As issues are closely interlinked with stakeholders, the next section will outline how to deal with the four stakeholder types identified in section 3.6.1.

3.8 Strategies for dealing with stakeholders

As already mentioned, Savage, Whitehead and Blair have classified stakeholders according to the assessment of their potential for threat and potential for cooperation, on the basis of attributes similar to Mitchell, Angle and Wood's power and legitimacy attributes. Here the stakeholders' capacity for threat is determined by their relative power and relevance to a particular issue (Savage *et al.*, 1991). On the other hand, stakeholders that do not pose a threat, but are cooperative to the organization are stakeholders that are dependent on the company. According to Savage *et al.* (1991), the more dependent the stakeholder is on a company the greater its willingness to cooperate will be (Savage, *et al.*, 1991:64). The strategies for dealing with the four stakeholder types are:

Involving strategy towards supportive stakeholders (type 1)

The strategy for dealing with supportive stakeholders is involvement in terms of keeping them informed. There should not be spent too many resources on this stakeholder class, as they have limited power to influence the development and direction of an issue. It is important to keep them informed and committed, as the support is important should the issue evolve into the public arena (stage 2 and 3). When supportive stakeholders are committed they do not disturb the process and they can be valuable in times of crisis.



Monitoring strategy towards marginal stakeholders (type 2)

Companies can deal with this stakeholder class by monitoring those stakeholders whose potential for both threat and cooperation is low. The aim of monitoring is to ensure that the circumstances do not change, for instance through alliances with other opponents or a sudden higher involvement in an issue.

Defending strategy towards the non-supportive stakeholder (type 3)

The best way to manage non-supportive stakeholders, according to Savage *et al.*, is through defensive strategies. Non-supportive stakeholders have power and the ability to affect issues. Also they do not agree with you, normally these are perceived as enemies. The purpose of using defensive strategies is to reduce the dependence that forms the basis for the stakeholders' interest in the organization. The type of defence used should be seen in relation to the respective issue's stage in its lifecycle. Depending on this, the company can choose between the different issues response strategies outlined in section 3.7.

The strategy towards enemies is to defend the organisation's view on the issue, but it is important to stress that defence does not exclude alliances with non-supportive stakeholders. According to Denise Deegan, a dialogue approach can even be recommended as a more successful way to deal with issues than just fighting and ignoring powerful pressure groups (Deegan 2001:22). While the

dialogue approach is most likely to be successful when implemented early in the issue lifecycle, the fighting approach should be postponed as long as possible, especially if the issue goes into the public arena.

Collaborating strategy towards the mixed blessing stakeholder

As the name of this strategy suggest, mixed blessing stakeholders are best managed through collaboration. This strategy implies that the company engages in transactions with its key stakeholders in terms of alliance building, relationships etc, with the purpose of exerting greater pressure on an issues' development (speed / direction) towards a positive resolution.

3. 9 Sum up – issues management and stakeholder theory

The presentation of the four generic strategies for dealing with stakeholders marks the end of the explanation of the issues management process. The issues management process has been outlined and tools for analysing issues and their potential to threaten the organisation has been uncovered. Furthermore, the theoretical framework has provided a tool to understand an issue's development through the issue lifecycle and the available response options to deal with issue at each stage of the lifecycle. The following will sum up the issues management process.

As we have seen in the previous sections, the *right* stakeholder approach is crucial to successful issues management, both in terms of identifying issues and if necessary when developing issue response strategies. In the issues management context, the right stakeholder approach is to have a framework that can identify stakeholders, analyse their position in terms of power, urgency and legitimacy and finally anticipate stakeholders' potential for threat or cooperation on issues in order to develop strategies to deal with issues and stakeholders.

The following will summarise the key concepts from the issues management and stakeholder frameworks that will be used to analyse the Letigen case and ultimately answer the problem formulation in relation to the three clusters presented in chapter 3.3.

1. Issue identification and its nature throughout the issue lifecycle

- Scan the environment for trends and issues

- Identify those of importance for achieving business goals and evaluate impact on performance (operations, financial or reputation)
- Prioritise and act on those issue that has a high probability of occurrence
- Identify the nature of issue
- Analyse and forecast the development of the issue lifecycle
- Identify the issue's place in the lifecycle.

Tools: issue evaluation checklist, the gap analysis concept, issue lifecycle analysis

2. Stakeholder identification

- Analyse and forecast stakeholder positions, power and strategies

Tools: the Diagnostic typology of organizational stakeholder model and the issue activation checklist.

3. Issue response strategies

- Analyse position and strategic options

Tools: gap analysis concept, issue lifecycle model applied strategic response options and the Diagnostic typology of organizational stakeholder model.

Having listed the tools and concepts that outline the issues management framework that will be used to conduct the case analysis, the following chapter will start out by identifying the Letigen issue, thereby marking the beginning of the case study.

Having presented the analysis framework, the following chapter will present the main concepts of issues management and stakeholder theory that the model draws upon.

4. Introduction to the Letigen case

The turning point of the case was Nycomed's Letigen pill, which they had sold and marketed since 1992. The product was targeted at severely overweight people and the product property was to speed up metabolism and reduce the users' appetite. Originally the product was developed by Arne Astrup, a nutritional specialist and, from 2002, a member of the Danish Nutrition Council. The components of the drug included several substances that were banned from the rest of the EU and the United States, but were still allowed to be marketed in Denmark. In the time the product had been on the market, some 700.000 people had at some point in time been prescribed the drug.

In addition to being targeted at severe overweight people, the Letigen pill had turned into a lifestyle drug and the pill was used by a large number of people outside the intended target group. Thus the pill became known as the "bikini pill". Women especially were managing to get their doctors to prescribe Letigen as a general slimming aide and not for strictly medical uses. The status of the Letigen as a lifestyle drug had created some sporadic media attention in past, and Nycomed were used to getting a few stories every summer on the subject, but these were quickly forgotten and never led to any increased public awareness.

Thus, when the Letigen issue re-emerged in the summer of 2002, Nycomed did not, based on the previous experiences with the issue, anticipate that the issue would develop into a full-blown crisis and media scandal. The issue that started out with just a few headlines in Ekstra Bladet, escalated, as we shall see later in the stage analysis, over the months to come, and resulted in a suspension of Letigen from the Danish market in November 2002.

One of the key factors for the development of the issue was the high degree of stakeholder involvement. The Letigen issue was simply very suitable for campaigning by activist groups. Winter & Steger's has, based on extensive research, developed an issue evaluation checklist which can be used to determine whether or not an issue has the potential develop through all stages of the issue lifecycle and develop into crisis (Winter & Steger 1998:34). By using their checklist (figure 13 below) it is possible to explain why the issue attracted stakeholder awareness in the first place.

Figure13 - Issue evaluation checklist

- Are the arguments against the issue plausible?
- Does the issue evoke emotion - is it understandable – visible by the public?
- Is the issue media friendly?
- Are there connections to other issues of the company or other companies?
- How strong is the key activist group?
- How far have the dynamics of the crisis already evolved?

Based on Winter & Steger 1998:34

Are the arguments against Letigen plausible?

According to Winter & Steger, two factors determine whether activists' claims are plausible: if (1) it is connected to some understandable concerns, and (2) it is communicated through a reliable and credible source (1998:34). For the Letigen issue both factors were present. In the general public there was already a focus on obesity as well as an ongoing concern about drugs and adverse side effects. Therefore when the Danish newspaper Ekstra Bladet picked up the story and presented a Letigen patient telling her story, and the fact that the Danish Consumer Association backed it up, gave the story credibility despite the media's tabloid status. In the initial phase, plausible arguments about Letigen and harmful side effects were presented to the public.

Does the issue evoke emotion?

This question is according to Winter & Steger the most important to ask when companies evaluate issues. In order for issues to evoke emotion they need to contain some of the following characteristics (1998:35):

- easily understood by the public
- visual
- touching

The Letigen issue was easily understood by the public and it was easy to relate to the patient who had suffered from harmful side effects who was presented in the media in July 2002, and it was relatively easy to build sympathy as many people would know someone who had used Letigen or had used the product themselves.

Is the issue media friendly?

The Letigen issue turned out to be extremely media friendly. As we shall see later there were no limits to how many new facts and angles there could be added to the story and the allegations of

harmful side effects and the deaths that could be related to the use of Letigen suited the media well. According to Winter & Steger, *“the importance of the media raising issues cannot be overemphasised, because media involvement is the way to bring an issue to prominence”* (1998:40). The emotional characteristics of the issue also suited the media as it provided content suitable for sensationalist headlines.

Is the issued connected to other issues of the company or companies?

Generally there was (and still is) a focus on pharmaceutical products that do not work as intended or have an adverse risk profile. The idea that people get sick by using medicines does not suit the public well. By the time of the Letigen issue, the Danish Pharmacists Association had publicised a list of older pharmaceutical products that they believed needed new testing and product résumés, among which Letigen was one of them. For the industry as a whole, the larger issue of adverse side effects was and is something that pharmaceutical companies have to deal with occasionally when a product is targeted.

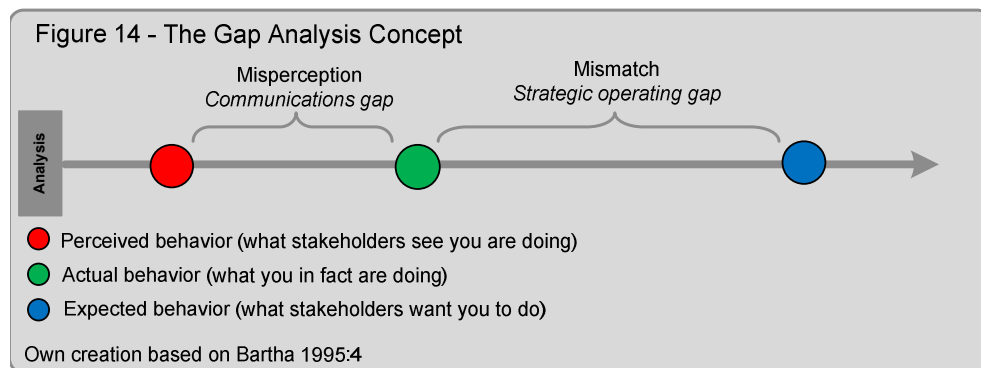
How strong is the key activist group?

The Danish Consumer Association (DCA) had a strong reputation in the public as the consumers' watch dog and their claims were usually regarded as credible. Thus by the time this group picked the issue up the alarm bells should have rung in Nycomed. With a relatively easy access to the media and an ability to collect case material against Letigen and Nycomed, the DCA had a high degree of power to influence the further development of the issue. Besides the DCA, another activist group was in play in the issue formation process - a couple which had experienced the harmful effects from Letigen in their own lives and were now devoted to collect cases to publish them on the internet. Though not as powerful as the DCA, they had a part to play in bringing the issue to the surface. Together, the above key factors were part of the creation of the expectations gap which laid the foundation for the Letigen issue and would continuously work together to build an increasing pressure towards Nycomed to do something about their product. The following part will examine the characteristics of the gap more closely.

4.1 Gap Analysis

“In an ideal world, there is congruency between what stakeholders want your organization to do (expectations), what they see your organization doing (perceptions) and what your organization is doing (reality). But in the real world there are gaps between the three concepts, which can pose major problems” (Bartha 1995:2)

The purpose of performing a gap analysis is to identify the nature of the gap and thereby gaining a better understanding of the specific issue, which is necessary in order to choose the appropriate issue response and stakeholder strategies needed to contain the issue and eventually close the gap. In order to see how Nycomed handled the Letigen issue, it is necessary first to find out whether they faced a perception issue or a strategic performance issue, as the two types of gaps between Nycomed and their stakeholders need different solutions to eliminate the issue. The gap analysis concept shown in figure 14 will be used to establish the nature of the gap that laid the foundation for the Letigen issue.



The first allegations that emerged against Letigen were that the drug had harmful side effects and the DCA advocated that the product should be removed from the market and, during the development of the case, several more stakeholders adapted the same position to the issue. In their eyes, Nycomed was marketing a product that was not safe to use did not expect a pharmaceutical company to sell products with harmful side effects. Therefore looking from a stakeholder perspective (activist and media perspective Ed.) the expectational gap was a strategic operating problem and, in order to meet expectations, Nycomed would have to withdraw the product and that way aligning corporate performance with stakeholder expectations. Nycomed's position on the other hand was that there was nothing wrong with the product.

The Nycomed position was that they had successfully sold and marketed the product for ten years and that the opposing stakeholders had their facts wrong regarding their alleged risk profile for Letigen. Therefore Nycomed refused to identify the issue as a strategic operating problem, but saw the issue as a perception gap that could be fixed by trying to change current perceptions of their performance at that time.

To sum up the gap analysis, the Letigen issue emerged because of a gap between Nycomed's performance and stakeholder expectations to how that performance *should* be. The general public's expectations of how a pharmaceutical company as Nycomed should perform i.e. expectations to the safety of use of the products the company sells in relation to the actual performance where a severe product safety issue was actually experienced with Letigen. This gap was identified by a few activist groups and by the media and was brought forward to public awareness. At the same time, as argued later in the stage analysis, Nycomed did not have same view of the issue / problem. In this early stage of the identification process the issue was identified by Nycomed as a perception issue i.e. and that the beginning allegations and advocating against Letigen was due to a misperception between stakeholders and Nycomed's actual performance.

The following section will analyse how the issue developed and account for the Letigen issue life cycle and how the issue developed in terms of increasing public pressure on Nycomed to change their operations. By examining public pressure and the issue lifecycle evolution, the development in the width of the gap can also be established. Furthermore, the next section will be based on the empirical data collected on the case and try to validate the lifecycle analysis framework that will be used to conduct the stage analysis based on the four stages in the Letigen issue lifecycle. Finally, the results from the lifecycle analysis can also be used to answer Winter & Steger's checkpoint as to *how far have the dynamics of the crisis already evolved?* which according to their framework is crucial when planning response to an issue as well as to the involved stakeholders.

4.2 Identifying the Letigen issue life cycle

In this section I will identify the development of the Letigen issue life cycle using the adjusted life cycle analysis framework based on Winter & Steger's public awareness framework presented in section 3.5.1. The results from this analysis will show how the issue developed through the lifecycle and it will make it possible to identify and place the issue in relation to the four stages of the

lifecycle development. This identification is necessary when assessing Nycomed's strategic options in dealing with the issue during the course of its development and the rising pressure from the public. In relation to the gap analysis, I have chosen to interpret the aggregated pressure which will be the result of this analysis, as a visualization of the expanding expectational gap between Nycomed and the involved stakeholders in the Letigen issue. The pressure (or negative public awareness) will be measured by aggregating the four following factors over time (the numeration below does not indicate to what extent one is more influential than the other):

1. Number of events triggering outside pressure (Facts regarding harmful side effects and deaths related to the use of Letigen)
2. Numbers of media involved in the issue (expansion of outside pressure in the public)
3. Level of importance (development of topics, i.e. the number of news stories presented in the media)
4. Stakeholder awareness (number of stakeholders involved in the issue)

I have chosen to process data according to the above four factors using a time frame that spans from July 2002 to December 2002, from emergence of the issue until it found resolution i.e. the suspension of Letigen from the Danish Market. Besides showing the historical development of an issue this methodology can also be used to forecast the future development of an issue. When analysing what Nycomed could have done differently in relation to the Letigen issue, the forecasting method will add an important perspective to this. Furthermore, by processing the data according to the above factors, the results will either fit or not fit within the issue lifecycle framework and will give an indication to whether or not the proposed issue response strategies vis-à-vis the four stages of the lifecycle will hold water. In other words, it will verify that the issue lifecycle framework can be used to describe the development of the Letigen issue. Lastly, in order to prove the general validity of the connection between the four factors I have chosen to conduct a correlation analysis on the results derived from each factor. Besides showing a correlation between the four factors, the correlation analysis gives an indication to how the four factors contribute to the understanding of the dynamics and interplay between the four factors that eventually could lead to a bandwagon effect amplifying the pressure during the issue development.

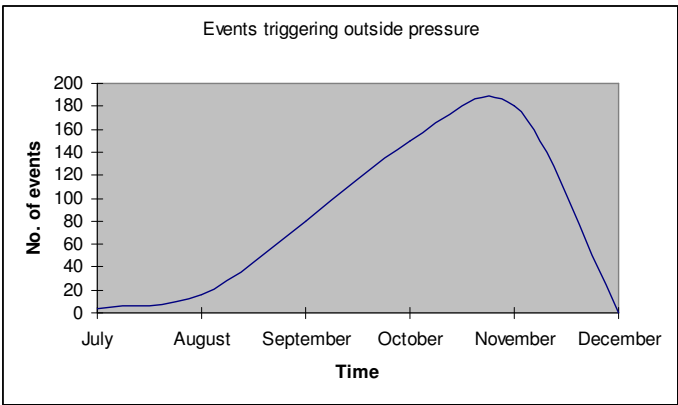
1. Number of events triggering outside pressure

The facts regarding harmful side effects and deaths related to the use of Letigen have been collected through case stories in the media, online resources and information from the Danish Consumers Association. The collection of facts have been structured according to the time scale from July to

December and added up on a monthly basis. The exact number of people who suffered from either harmful side effects or died from the use of Letigen has varied depending on which media or interest group that presented the facts. I have chosen to add up the highest number of facts presented by any of these groups each month, as the dramatic element played an important part in the development of the issue. The results from the data collection for the number of events triggering outside pressure are:

	July	august	September	Oktober	November	December
Events triggering outside pressure	4	16	80	150	180	0

By converting these numbers into a diffusion curve we get the following pressure indicator for events:

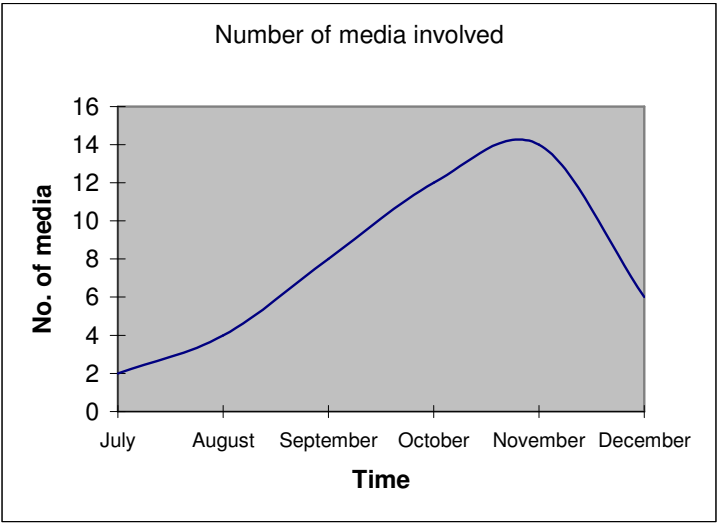


2. Numbers of media involved in the issue

According to Winter and Steger, the media have a critical role in bringing the issue to public attention, therefore the number of involved media is also an important pressure indicator in that the more media involved the more likely the issue will reach the top of the agenda (1998:41). In order to identify the number of media involved (involvement was determined to the fact that the media in question had reported one or more stories regarding the Letigen case), I have conducted a database search in InfoMedia, and trawled the internet for information on dates for news stories on Denmark's Radio and TV2. Then the number of different media was added up on a monthly basis in the selected time span. The results of the media involvement analysis are:

	July	August	September	October	November	December
Number of media involved	2	4	8	12	14	2

By converting these numbers into a diffusion curve we get the following pressure indicator for the development in media involvement:

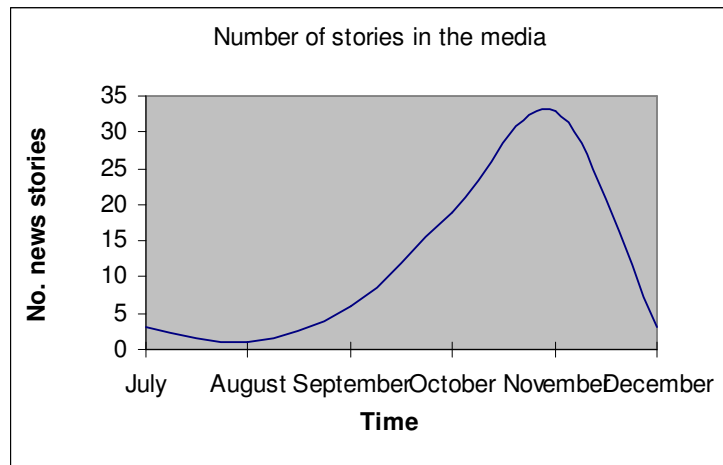


3. Level of importance (number of news stories)

In order to count the number of news stories that was printed or broadcasted during the time period, the same methodology was used as in Ad.2. Press clippings were collected that dealt with the Letigen case, categorized in relation to date of publishing and added up the number per month. Just like the number of *media* that were involved in the issue indicates pressure, the number of *news stories* also is a strong pressure indicator towards the focal company, as well as indicating the place of the issue on the public agenda. The results of the enumeration of the news stories are:

	July	August	September	October	November	December
Number of stories in the media	3	1	6	19	33	3

By converting these numbers into a diffusion curve, presented below, we get the following pressure indicator for the level of importance, i.e. the role of media coverage in the creation of the Letigen issue lifecycle:

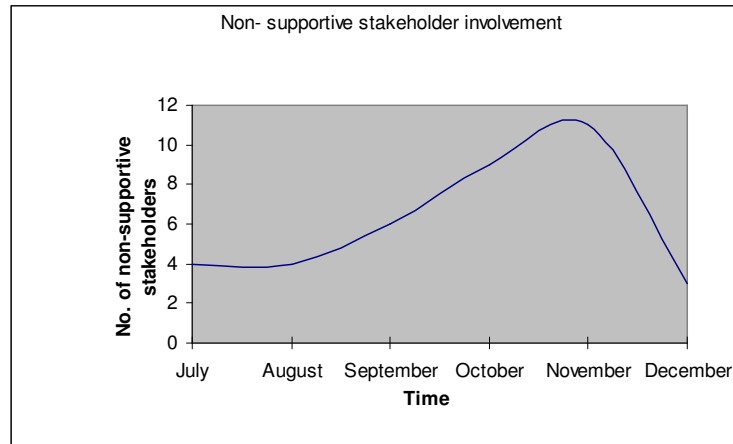


4. Stakeholder Involvement

As stated in the theoretical framework, stakeholders are one of the key factors to the emergence of issues. Following that line of thought the number of non-supportive stakeholders involved in an issue also indicate to which extent a company is under pressure from its external environment. Stakeholders were identified either through their communication / issue advocating in the media or through the conducted interview with Nycomed. The information on stakeholders was categorized in relation to the time and length of involvement in the case, i.e. a stakeholder that was involved during whole time period counted as one in July, August, September, October, November and December, whereas a stakeholder who was only involved in November, was only counted in for that month. The involved non-supportive stakeholders were then added up for each month.

	July	August	September	October	November	December
Non-supportive stakeholders involved	4	4	6	9	11	3

Converting these numbers into a diffusion curve, gives us the following pressure indicator for stakeholder involvement in the Letigen issue.

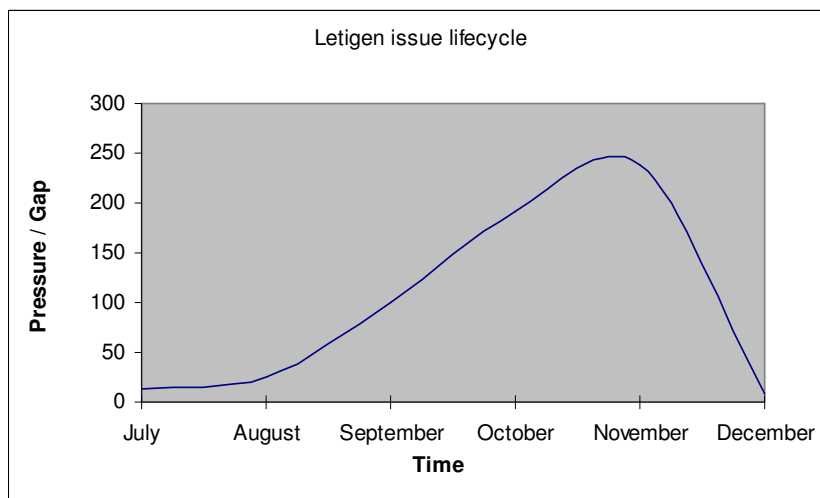


4.2.1 The Letigen issue lifecycle

By aggregating the results from the four pressure indicators, it provides us with a visualization of the development of the overall external pressure posed on Nycomed over the time period, and by inserting the aggregated data into a diffusion curve we get the Letigen issue lifecycle. The aggregated results are:

	July	August	September	October	November	December
Events triggering outside pressure	4	16	80	150	180	0
Number of media involved	2	4	8	12	14	2
Stakeholders involved	4	4	6	9	11	3
Number of stories in the media	3	1	6	19	33	3
Letigen issue lifecycle	13	25	100	192	238	8

The visual representation of the Letigen lifecycle can be seen in the diffusion curve below.



Correlations between the pressure indicators

In order to establish that there is a positive connection between the four pressure indicators that construes the Letigen issue lifecycle, I have performed a correlation analysis on the aggregated results. The correlation analysis has been conducted in an Excel spreadsheet and as the following diagram shows, each of the four pressure indicators has been labelled the numbers 1-4. I have then used the correlation formula in Excel to carry out the actual analysis. The results from the analysis are presented in figure 15.

Number	Pressure indicator	July	August	September	October	November	December
1	Events triggering outside pressure	4	16	80	150	180	0
2	Number of media involved	2	4	8	12	14	2
3	Stakeholders involved	4	4	6	9	11	3
4	Number of stories in the media	3	1	6	19	33	3

Figure 15 – Correlation analysis

Variables	Correlation score	Comment
1 and 2	99,60%	There is a positive correlation between facts presented facts and number of media. Being close a 100 % positive
1 and 3	99,04%	There is a strong correlation between stakeholder involvement and facts, thus indicating that this combination was very influential on the issue development
1 and 4	93,49%	Again the correlation between facts and media coverage is positive, which can be documented empirical research where the presentation of facts was mostly presented through the media
2 and 3	98,14%	The correlation between stakeholder involvement and media involvement is positive, though not 100%, but still indicates that media involvement affect stakeholder involvement and vice versa.
2 and 4	91,27%	The correlation between number of media involved and number of stories in the media has made the lowest score. An explanation could be that the media involvement is not proportional with media coverage, which is also reflected in the fact that a few media were more aggressive and persistent in their coverage and published the most stories.
3 and 4	96,23%	The clear correlation between non-supportive stakeholders and number of stories in the media suggest that these two factors also in a high degree influence each other.

Source: Own creation

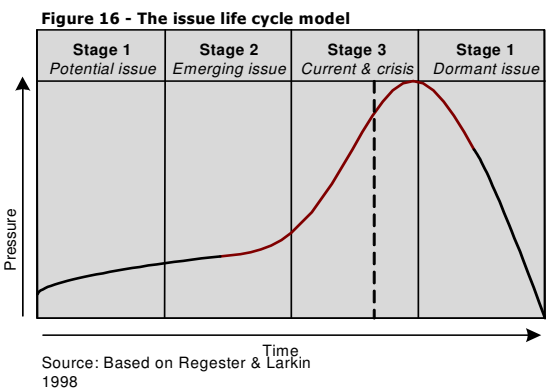
In order to determine a correlation between the included variables the correlation score should be close to or equal 100 percent. Thus by looking at the results from the analysis one can conclude that all of the above variables were connected and influenced each other in affecting the development of the Letigen issue and to build the increasing pressure against Nycomed that took place during the span of the case. Also it proves the validity of the lifecycle model as a tool that can be used both to describe how the issue developed, but also as a proactive forecasting method, as presented by Winter and Steger (1998:60). By stating the general validity of the lifecycle model, I can then

presume that the generic issues response strategies can also be applied both to describe how Nycomed responded to the issue and what they could have done differently.

4.2.2 Applying stages to the lifecycle model

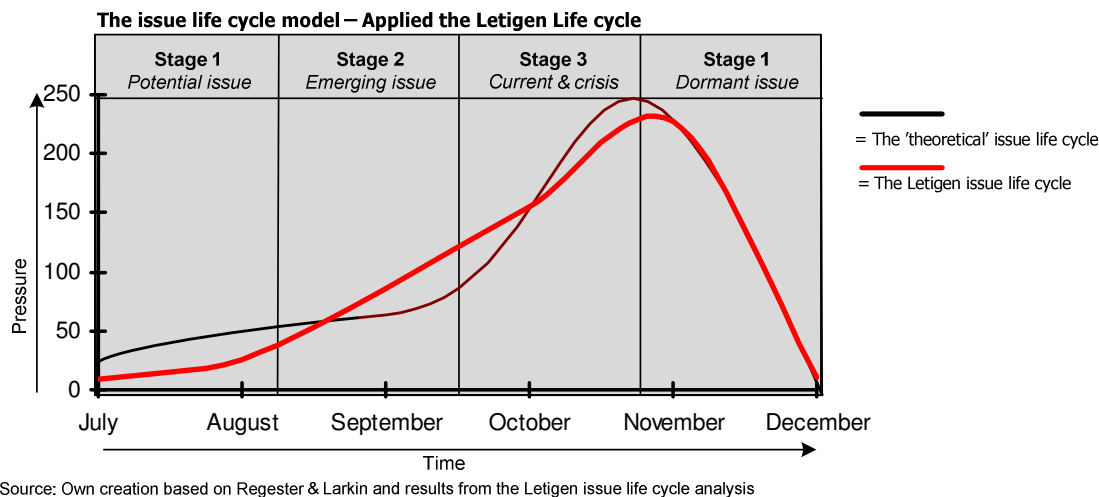
In order to be able to apply the lifecycle analysis to the Letigen case study, it is necessary to identify the four different stages (the potential, emerging, current & crisis and dormant stages) in the lifecycle as shown in the theoretical issue lifecycle illustration in figure 16 below.

As explained in the theoretical framework, each stage holds different characteristics that determine



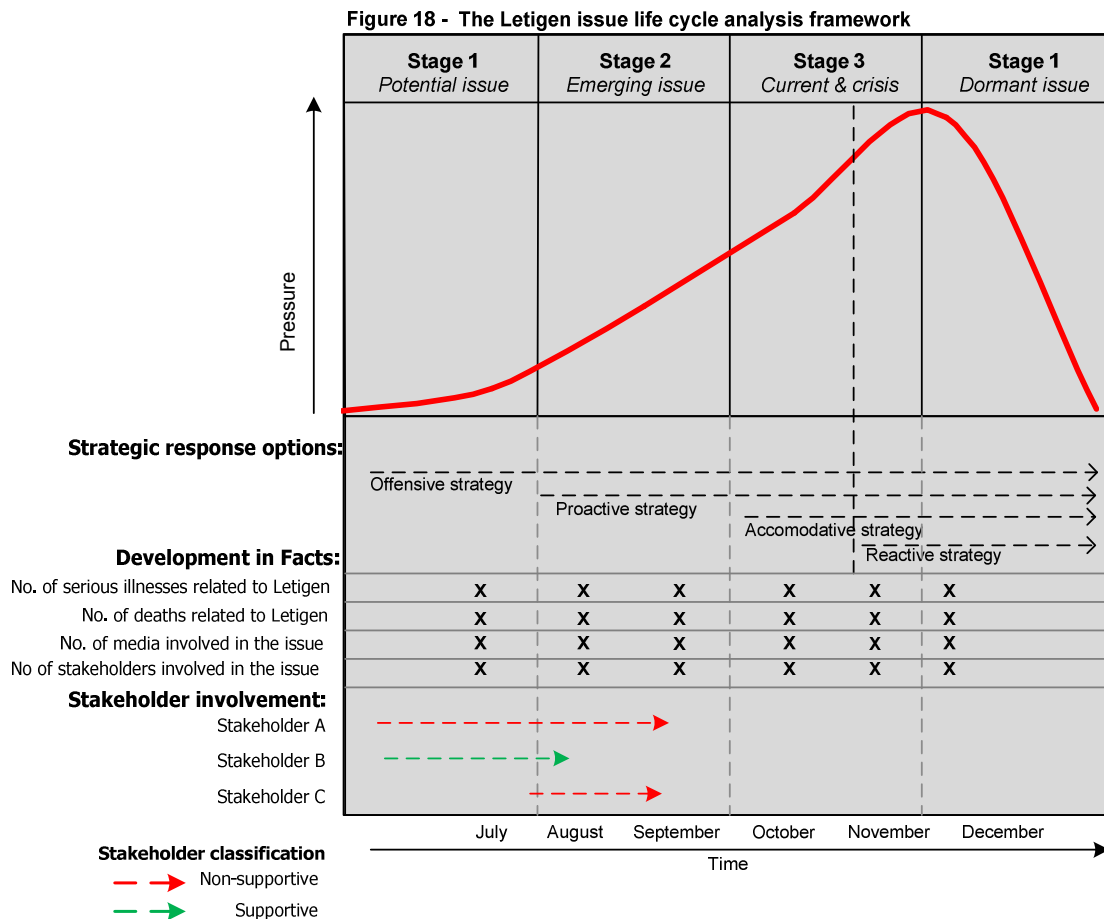
whether or not the issue will develop further or disappear. Thus, by knowing in which stage the issue is placed in the lifecycle, one can determine the strategic options available for the company. In the following model I have applied the Letigen issue to the basic issue lifecycle model presented above, thereby identifying the four stages of development for the Letigen issue. The reasoning for the

placement of the issue in each stage will be described in the following stage analysis in chapters 5 to 8. The issue lifecycle model applied the Letigen issue can be seen below in figure 17. The similarity between the developments of the Letigen issue in relation to the theoretical issue lifecycle model is evident, thereby justifying the usability of the chosen framework in order to analyze the Letigen issue.



4.3 Setting up the stage analysis framework

The purpose of following part is to connect the Letigen issue lifecycle model with the strategic response framework and stakeholder-mapping framework in one model that can be used to structure and conduct the Letigen stage analysis. The model will be explanatory and contain the Letigen issue lifecycle, the four identified pressure indicators, strategic response options available in each stage for Nycomed and finally the development in supportive and non-supportive stakeholders in relation to the specific case study. By doing this we get the issue lifecycle analysis framework, presented in the figure 18 below:



Having presented the model that will lay the foundation for the overall structure of the following stage analysis, the following section will go through the issue development in stage 1, and thereby beginning the work of examining what went wrong in the Letigen crisis and what could have been done differently.

5. The Letigen case

The purpose of the stage analysis will be to identify the key events and stakeholder involvement that made the issue escalate into crisis through stage 1 to stage 3, and also on Nycomed's response to those events. The fourth stage of the lifecycle will only be commented upon briefly as the issue was resolved in stage 3.

5.1 The Letigen issue lifecycle - Stage 1

The Letigen issue was both a potential and dormant issue for some years. When the issue resurfaced in July 2002 it was not the first time Letigen received criticism and negative media attention. The issue had emerged before, but had never developed into a crisis. According to Bigelow et al (1993) issues can move through the lifecycle without reaching resolutions, *"...and that issues are never resolved in the final sense – they simply become dormant and may arise later when those negatively affected seek to initiate change"* (Bigelow et al, 1993 p. 23).

Nycomed's past experiences with the Letigen issue had been in the form of short-term media attention on a regular basis with the focus on women taking Letigen to loose weight before the bikini season. Therefore when the issue entered the potential stage in the lifecycle this time, it was not prioritized as a potential threat to the organization. As a Nycomed representative put it *"the issue appeared on a low level every year around summer time, and it was considered internally that it was just something they had to put up with, as with any other controversial product, therefore the thinking was that we'll get that every year, and that's the way things are, So it came as a bit of a surprise to the company when the issue really took off in the end of last year. And I think that throughout that process there was an expectation that the issue would die out, but it kept going...kept rolling"* (Interview with Nycomed 2003).

However, this time the issue was much more powerful than the earlier appearances, because of the following issue survivor factors:

- The issue was defined when a Letigen "victim" and her husband (Randi and Johnny) set up a website with the purpose of collecting information on Letigen and other people's experience with adverse side effects from the pill in the year 2000. To this a Nycomed communication officer stated regarding emergence of the issue *"Actually the issue was also driven by this one man and his wife, who made a website dedicated to collect material and cases of side effects to*

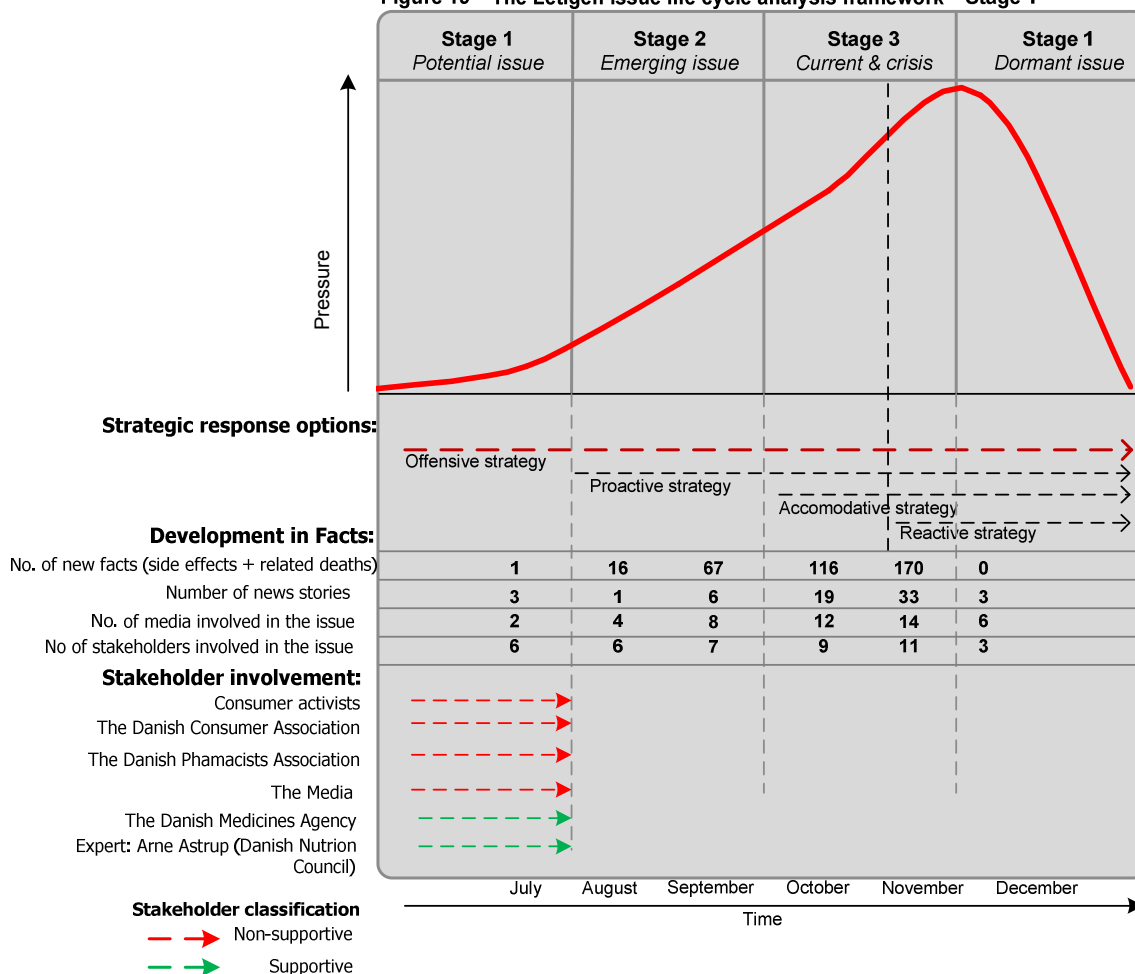
the Letigen drug. This shows how little engagement there was to this case in the beginning, and then they opened the ball game in Tænk & Test and they had a lot of letters coming in telling about this and that, on adverse side effects.”(Interview Nycomed 2003)

- Ekstra Bladet picked up and published Randi and Johnny’s story on the 4th of July 2002, and Letigen was for the first time related to serious adverse side effects. This created a powerful symbol which other stakeholders could pick up and use to drive the issue further, as in the statement from Wartick and Mahon, *“Many issues go unrecognised until some sudden, unforeseen event galvanises the public”* (Wartick and Mahon, 1994, p. 300)
- Issue champions (stakeholders with high credibility) entered the arena and gave the issue momentum (Arne Astrup and The Danish Pharmacies Association)
- The Danish Consumers Association started to campaign on the issue by collecting reports on Letigen and adverse side effects.

According to the issue lifecycle framework, these combined factors gave birth to an issue survivor, i.e. an issue that had the potential to move into the next stage of the lifecycle to become an emergent issue. Figure 20 (p. 51) lists the key events that helped define the issue in stage 1..

Figure 19 below gives an overview of the development of the issue in stage 1. The development is illustrated in terms of stage in the issue lifecycle, pressure indicators and stakeholder involvement. The figure will also be used when discussing Nycomed’s response to the issue in this stage. As the figure shows, there was relatively little pressure on Nycomed to act on the issue in stage 1 of the issue lifecycle. The media attention was limited to a story in Ekstra Bladet, a tabloid newspaper, and a follow up story on DR Nyheder, so it was nothing Nycomed had not experienced before. However, when Letigen re-emerged as a potential issue, a wide range of stakeholders were quick to pick up and get involved in the issue..

Figure 19 – The Letigen issue life cycle analysis framework – Stage 1



Source: Own creation

The first stakeholders involved were the consumer activist couple and Ekstra Bladet. Interestingly, the DCA, the Danish Pharmacists Association and Arne Astrup quickly *piggybacked* on the issue, offering non-supportive statements – an event to which one could conjecture that these stakeholders had motives to use the opportunity to position themselves in the debate (see figure 20). Stakeholders' supportive or non-supportive stance to the issue is marked by green and red arrows in the figure. The arrows do not dictate to which degree they are involved, but the following stakeholder mapping and analysis will seek to uncover this.

Figure 20 - Key events and statements in Stage 1 – Potential issue

July 2002

04/07-2002. Ekstra Bladet publishes a story about a woman, Randi, who experienced severe adverse effects from the use of Letigen. DR1 News makes a follow-up story on the issues the same evening. Both the Danish Medicines Agency and Nycomed characterize the case as extremely rare. Nycomed communicates to the public that Letigen is a product that can be used safely.

05/07-2002. The Danish Consumers Association (hereafter DCA) receives four complaints during the day about serious adverse effects that could be a result from using Letigen, and requests that Letigen should be withdrawn from the market, until there has been conducted new product tests and that it can be documented that Letigen can be used without risks of any severe adverse effects and complications.

05/07-2002. The Association of Danish Pharmacies, request that Letigen should be unregistered. The developer of the drug and chairman of the Danish dietary council, Arne Astrup underlines that Letigen should only be used in cases of severe overweight.

12/07-2002. DCA now has six reports of incidents about severe adverse effects that could be caused by the use of Letigen. The Danish Medicines Agency estimates that severe overweight contains more risk factors to health than Letigen.

Source: www.slankogsyg.dk

5.3 Stakeholder Mapping stage 1

An important part of developing an effective response to an issue is to identify those stakeholders involved in the issue and those who could get involved at a later stage in the issue's lifecycle, "*Of all the possible stakeholders for an organization, the ones who will be **relevant** to the organization's executives depend on the particular **issue***" (Savage et al, 1991. p.149). As mentioned earlier several stakeholders entered the arena after Ekstra Bladet published Randi's story the on the 4th of July, 2002. The following part outlines the stakeholders who were involved in stage 1 according to their supportive or non-supportive stance on the issue.

Non-supportive stakeholders

Consumers

The consumer stakeholder group was, in stage 1, limited to current and potential users of Letigen. Consumers that use Nycomed's products expect that the products work as promised without any risks. Nycomed has a wide portfolio of products targeted at different disease areas and sell OTC (over the counter) products as prescription drugs. The consumers' stake in the Letigen case is two-fold. The large percentage of current and former users of Letigen who had never experienced adverse side effects and then there was the consumer activist couple who drove the issue from the

beginning. An estimated number of 790,000 people had used Letigen when the issue surfaced, and in 2002 the estimated number of people that were using the product was approx. 100,000.

In Savage et al's stakeholder mapping framework, consumers can be classified in the "mixed blessing" category of stakeholders, in the sense that they can influence the organization positively or negatively in times of crisis, and in terms of their potential to cooperate or threaten the organization. If Mitchell et al's dynamic framework is taken into account, mixed blessing stakeholder's have the potential to move to the non-supportive stakeholder category thereby posing a bigger threat to the organization. In stage 1 of the Letigen issue development, the consumers in general will be placed as mixed blessing stakeholders and the consumer activist couple as non-supportive stakeholders. This categorization is based on a conjecture that the consumers have a high potential to threaten Nycomed's performance and little potential for co-operation.

The Danish Consumer Association (DCA)

The DCA had, on a previous occasion, printed an article in Tænk & Test (The DCA's monthly member magazine) in January 2000 stating that Letigen was life threatening. When the Letigen issue re-emerged they used the opportunity to pick up the issue and campaign against the product. A conjecture regarding the DCA's stake in the issue was that they at the time needed an issue or case with which they could profile themselves. So their stake was two-fold. Firstly, as the consumer watchdog group, their purpose is to make sure that consumers can safely buy and use any company's products. Secondly, in order to be effective and have power against the companies they campaign against, they need to take single cases and follow them until they get the outcome that can be used to positively increase their reputation with their members and in the public. This second stake in the issue is reflected on by a Nycomed representative who in the discussion on the DCA's role in the case stated, "... *I don't think they sat down and speculated on the issue. Of cause they reacted on some of the stories they had heard about people that might have been killed by Letigen. And I think it became more and more obvious that they had an agenda of their own*" (interview with Nycomed 2003)

The DCA would under normal circumstances be categorized as a marginal stakeholder with either high threat or cooperative potential, but certain issues such as product safety could activate a marginal stakeholder, causing their potential for threat to increase (Savage et al, 1991, p. 150). This

is exactly what happened in the Letigen case, where the DCA picked up the issue and started to campaign against Nycomed as soon as the issue re-emerged. The DCA's focus on Letigen and their decision to fight to get Letigen banned from the market was a significant factor for the further development of the issue.

Danish Pharmacists Association (DPA)

The DPA Published in an open letter a list of 20 products that needed to be re-evaluated by the Danish Medicines Authority (DMA) and should undergo further testing. The DPA supported the consumer association in their demand to remove Letigen from the market. A conjecture on the DPA's stake in the issue could be that since they were the ones actually selling the product, they could profile themselves as a responsible actor by demanding that the product should be taken off the shelves. This assumption is supported by Nycomed's representative, who stated that, *"I noticed that last year about the same time as the Letigen issue took off, the pharmacists association wrote an open letter immediately after the Letigen case showed up, where they described a longer list (app. 20 different products) of products where Letigen was pinpointed, where they said that these products should be taken off the market, so they had an agenda going on at the same time"* (interview with Nycomed 2003)

By their opening statement to the debate that Letigen should be taken off the market, the DPA classified itself as a non-supportive stakeholder. As an industry association they positioned themselves on the side of the consumers and a conjecture is that their involvement significantly influenced the issue to develop further.

The Media

There is no doubt that without the media the issue would never have escalated into the crisis state. To some extent the media was the stakeholder group that drove the whole issue in stage 1 and onwards. Ekstra Bladet, which picked the story up, lives on sensationalist stories. The more interesting the story gets the more media wants to join in. The number of media escalated during the case as will be discussed later in the analysis. A Nycomed representative explained the media's role as such, *"As I see it there was a reason why it turned as a case in the first place and it is based on journalistic working methods, it is very obvious that it should be – there were some good stories – more or less documented"* (Interview with Nycomed 2003). Even though the media exerted

“relatively” little pressure on Nycomed in stage 1 it is still a dominant stakeholder. It is not a new thing either in Danish or international media that sensationalist and aggressive stories make it to the front pages. Ekstra Bladet was clearly on the consumers’ side and during the entire issue lifecycle campaigned hard against Nycomed. As we will see during the analysis of the next stages of the lifecycle, as more stakeholders got involved in the case, more and more media followed the story and mostly with a negative focus on Nycomed.

Based on the media’s critical stance to the issue regarding Letigen and their focus on the cases where people suffered from side effects, the media is categorized as non-supportive stakeholders. This is underlined by Savage et al’s framework where the media has high potential for threat for Nycomed and little potential for cooperation.

Supportive Stakeholders:

Danish Medicines Authority

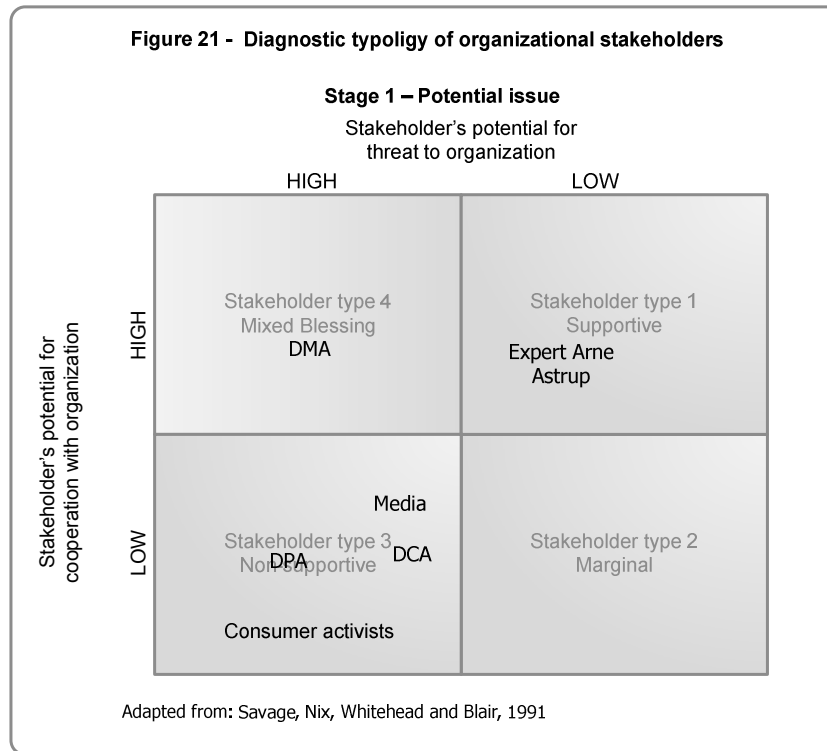
DMA is the authority that approves all drugs sold on the Danish market. DMA approved Letigen when it first was introduced. The Letigen issue became a credibility issue for DMA, due to the fact that a former employee from Nycomed was the person in DMA who approved the drug for the Danish market.

The DMA falls under the mixed blessing category in Savage et al’s framework. In the Letigen case the DMA had the power to support the continuing sale of Letigen, but also the power to remove the product from the market. In stage 1 of the Letigen issue lifecycle the DMA supported Nycomed on their right to market the product.

Experts

The first expert to enter the debate was the original inventor of Letigen, Arne Astrup who, with the reputation as an expert on the obesity field, would come to play a key role during the development of the issue. Arne Astrup had several agendas concerning the issue, as we will see in the analyses of the following stages. In stage 1 he was supporting his own invention and thus Nycomed who was the new owner and seller of the drug. Arne Astrup had – due to his expert status – a high potential for threat to Nycomed, but in stage 1 he was supporting Nycomed. Therefore he is categorized as a

supportive stakeholder. The above stakeholder identification gives us the following stakeholder map presented in figure 21 below, for the Letigen issue in stage 1



Supplementing the stakeholder mapping with Winter & Steger's framework for identifying outside pressure groups and their potential for exerting pressure in terms of publicising issues, lobbying governments and influencing consumers (1998:12), the identification of the DCA and their involvement in the issue in stage 1, was a clear indication that the Letigen issue had the potential of becoming an activist issue. In relation to the conjecture that the DCA had an agenda of their own, fits well into Winter & Steger's "Activist Checklist" presented in figure 22, as to why they decided to get involved in the issue in the first place.

Figure 22 – Issue Activist Checklist

- The issue should have a clear aim or goal.
- The issue should be easily understood by the public.
- The issue has a high symbolic value.
- The issue has the potential to damage the image of the company.
- The opponent is strong enough (no "underdog" effect).
- The issue can be packaged in a campaign in which the public can get involved.
- There are solutions that are confrontational, not gradual
- There could be a dramatic element to the campaign to engage the media.

Source: Winter & Steger 1998:83

5.4 The Issues management process stage 1

In line with the theoretical framework, it is in stage 1 that companies should systematically scan the environment to identify potential issues because *“Identifying issues early in the lifecycle provides the opportunity for a thorough analysis of their potential impact on the company and the development of effective solutions before the organizational environment becomes frenetic”* (Camillus and Datta, 1991. p. 70), and after identification, the issue as well as stakeholder positions and their ability to influence the further development of the issue should be analyzed. As a Nycomed representative explained, looking back on the early issues development, *“we did not have an issues management system set up at the time, and when you have a case coming up like this we would have had this stakeholder dialogue at a much earlier stage and we would have been in a more credible position from the beginning”* (interview with Nycomed 2003). On the basis of the above statement a conjecture could be that Nycomed had not conducted the necessary environmental scanning as well as an issue and stakeholder analysis, in order to proactively anticipate the issue’s further development.

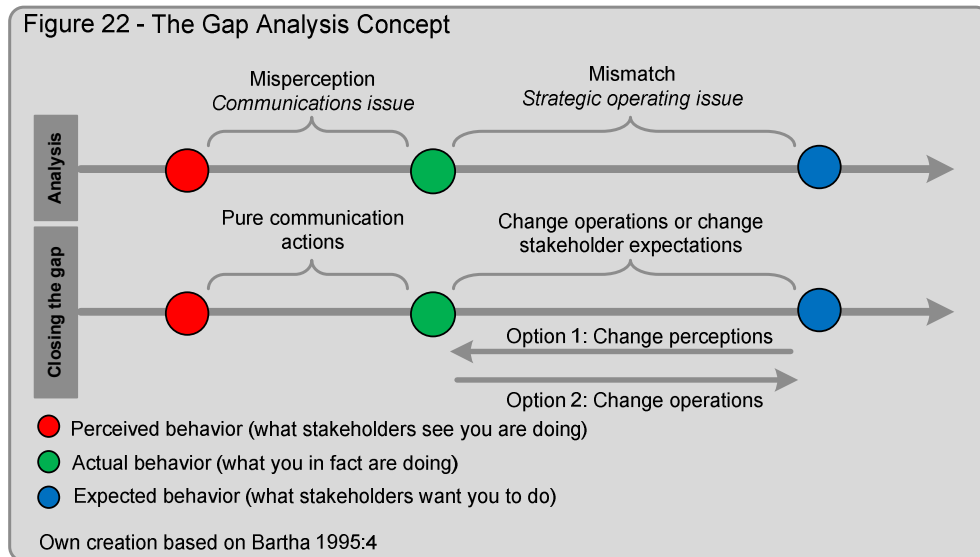
5.5 Response strategy stage 1

“One can hardly overemphasize the importance of an early identification of the relevant issues, which provides organizations with a longer response time to develop proactive strategies” (Camillus and Datta, 1991. p. 70).

According to the issue lifecycle analysis framework, companies can adopt an offensive strategy in stage 1, in order to resolve the issue. Having identified the gap as a strategic operating problem the strategic options at this stage would be to try to either change operations or change stakeholder perceptions. The following will show that Nycomed in stage 1 did not pursue this opportunity by instead adopting a laissez-faire strategy, i.e. doing nothing.

Nycomed kept expecting the storm to blow over as it had done several times before since it first surfaced in 1999. But this time the issue wouldn’t go away and stayed on the agenda. The management thought it could silence the critique by not adding any wood to the fire by partly ignoring the media stories. Furthermore, there was a internal belief in Nycomed that the product had and still was actually helping a lot of obese people getting better as can be seen in the following statement: *“....internally people thought that the issue would go away...it was essentially about the*

safety of a medical product because if it was used correctly it could save the lives of many other people”(Interview Nycomed 2003).



Nycomed’s reaction to the stakeholder attention (media and other stakeholders) in stage 1 can in terms of the gap analysis concept be described as trying to solve the emergent issue as a communications problem, i.e. there was a misperception among some stakeholders that product had harmful effects, therefore we answer them by stating that this is not the case and that the product was safe to use. Had Nycomed on the other hand conceived the problem as a strategic operating issue in this stage, their course of action might have been different.

“Once identified the issues need to be categorized into (1) those that have adequate clarity for immediate action and (2) others which lack clarity and need to be closely monitored until a clearer picture emerges” (Camillus and Datta, 1991. p. 70) [...] “The priority of an issue would obviously depend on a variety of factors, namely, the strategic relevance, the estimated cost-effectiveness (as measured by the impact of the issue) and the urgency (measured by the time period in which action is to be taken” (Camillus and Datta, 1991. p. 70).

But what were the real options? Due to the fact that the issue had already been up previously without being resolved, one should think that Nycomed management would be ready should the issue surface again. This was not the case. The perception in the company was influenced by the

previous incidents with the issue where it emerged, reached the current stage but never evolved to a crisis.

Looking in the rear view mirror, representatives from Nycomed stated the following offensive strategy options, which in their opinion would have been too aggressive in relation the stage of the issue. A question whether the responsibility of the issue solely lays within the producer of the drug the answer was: *“Yes it does and that is another interesting area. We could have said that we’re not doctors and it is up to doctors to prescribe the right amount of medication, but as a pharmaceutical company we are not interested to put the blame on doctors.”* Another informative answer was: *“Also what didn’t come out was that some of the people complaining about side effects from Letigen were drug addicts and alcoholics, and we could not have said that to the media [...] ...but in more general terms I think that this case also shows us that within the population are a growing concern about side-effects.”*

5.6 Sum up stage 1

“Officially or externally too little was done too late and that is maybe one of the reasons why the issue took off and exploded last year.” (Interview with Nycomed 2003)

The consequences for not having an issues management practice in Nycomed was that they did not conduct the necessary scanning of their external environment that could have identified the Letigen issue as a potential threat for the organisation. Following the theoretical framework, an issues management approach could have changed the course of events in stage 1 if Nycomed had:

- Scanned the environment
- Identified the Letigen issue and its potential for development
- Identified the nature of the expectational gap, i.e. the issue as a strategic-operating problem vis-à-vis the expectations of the involved stakeholders in stage 1.

The results from the issue analysis and stakeholder identification would have provided Nycomed with the option to engage in an offensive strategy in order both be in control of the agenda and second to close the gap. An offensive strategy at this stage would provide two options for Nycomed to close the expectational gap, 1) to change perceptions of the non-supportive stakeholders to match actual behaviour or 2) to change operations to match the demands of the stakeholders. At this stage

matching demands of stakeholders would not necessarily mean that Nycomed should withdraw the product, but by a dialogue approach towards the non-supportive stakeholders, try to find a solution that could benefit both parts, i.e. attempt to create a win-win situation. According to theory, an offensive response strategy could also imply that a solution could actually exceed stakeholder expectations and in this way, use the issue as a possibility to strengthen the company's reputation in its external environment.

Looking back at the issues lifecycle model, Nycomed did not enter the public debate in stage 1. As a consequence of not having approached the issue strategically in stage 1 in an organized manner, Nycomed did not have great possibilities of interaction. Thus the issues response and implementation in the issues management model could only be conducted and implemented on an ad hoc and reactive basis. Another consequence for not systematically conducting issues management in this stage was the failure to identify and classify the importance of DCA's involvement in the issue from the beginning. If there is a match between the issue checklist (presented in page 36.) and the activist checklist (presented in page 55) a company faces a "hot issue" that requires immediate attention (Winter & Steger 1998:79). In this case, by not responding to the issue in stage 1, Nycomed were on the way to leave the initiative to the DCA to set the agenda for the further development of the Letigen issue.

By not having implemented an issues management system in their organisation Nycomed did not get the "early warning" signals that this time around the Letigen issue would take the leap into stage 2. Nycomed's response to the assumption that the reason why the issue kept rolling was that they were not prepared, and replied to this assumption in the following way: *"Saying that that is the reason why it exploded last year is not entirely correct – it is more or less a coincidence [...] It just happened last year; it could have been the year before or next year, or three years from now. So it's more a phenomenon showing what could go wrong when you don't have a very specific issues management system set in already when you have the small indications on an emerging issue"* (interview Nycomed 2003).

Looking at the Letigen lifecycle analysis framework and summing up on the issue and stakeholder analysis several factors were now present in the Letigen issue that should have made the alarm bells ring at Nycomed. The media involvement and the presentation of allegations against Letigen

regarding harmful side effects as well as the interest in the issue of a powerful activist group should have indicated that the company faced a hot issue. In the failure to identify the issue in this stage as a threat to both product and ultimately corporate performance, Nycomed both missed the opportunity to implement an offensive strategy to close the expectational gap between Nycomed and the involved stakeholders and also missed out on the opportunity to forecast the further development of the issue into stage 2 of the issue lifecycle.

6. The Letigen issue lifecycle stage 2

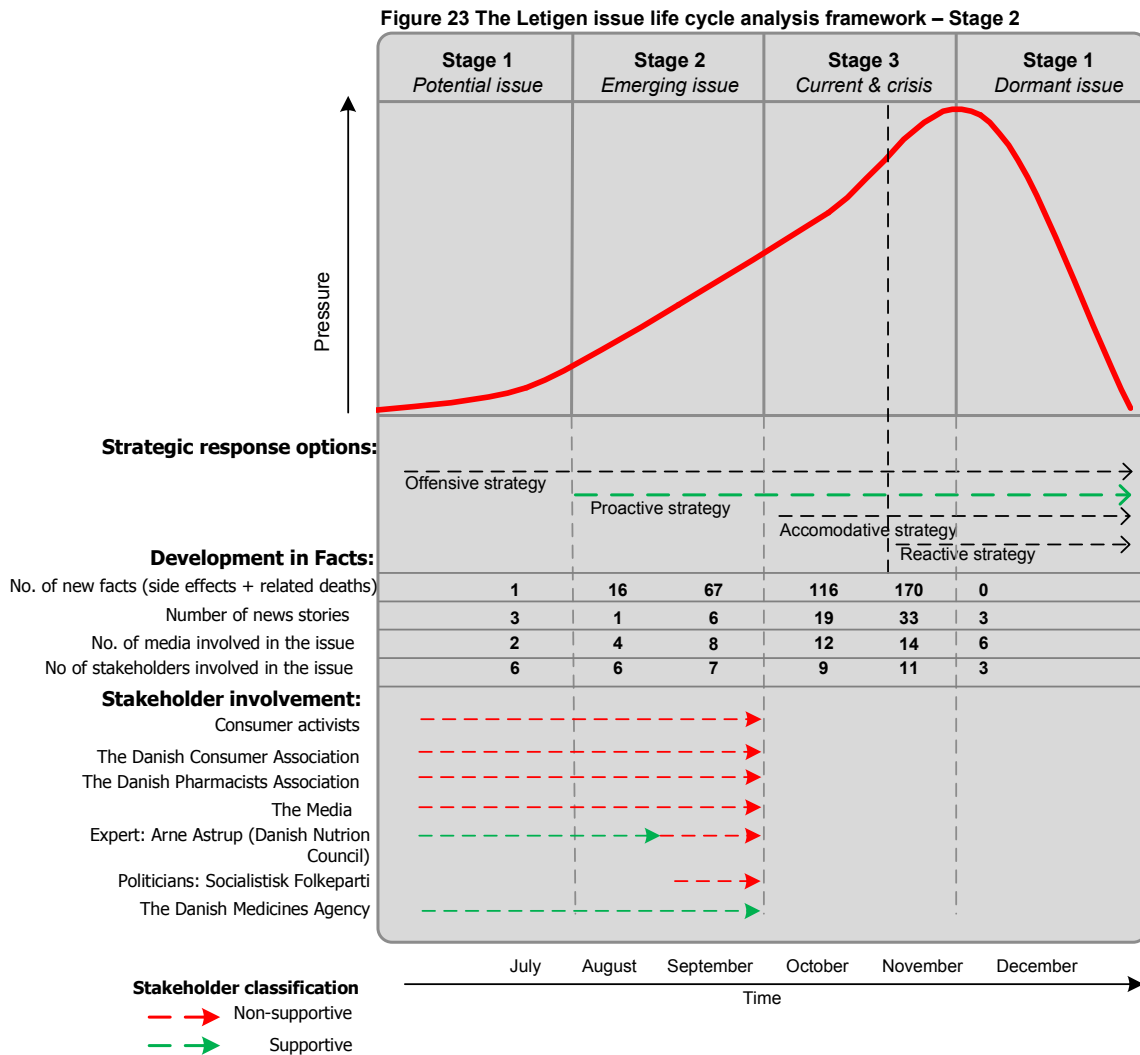
Emergent issues can be characterized by a “*gradual increase in the level of pressure on the organization to accept the issue. In most cases, this increase is the result of activities by one or more groups as they try to push and legitimize the issue*” (Regester & Larkin 1998:50). This fits well with the development of the Letigen issue in stage 2. A dominant factor for the further development of the issue in this stage is the media and its influence on the public opinion formation, and “*as momentum builds within the mass media, the issue becomes amplified into a public issue that may become part of the public policy process [...] and before the issue reaches the next stage, those involved usually try to attract media attention as a means of progressing the issue*” (Regester & Larkin 1998:50,51). These statements underline the development of the Letigen issue. Reading through the key events in stage 2 in Figure 24 one can deduce that stakeholder awareness was increasing both in terms of stakeholder involvement and in the amount of media coverage. An important factor for the development in stage 2 was also in terms of the public policy process that members of Folketinget (Danish parliament) began to take interest in the issue.

The DCA’s continued collection of facts and evidence regarding adverse side effects related to Letigen and the media’s willingness to bring these stories had an explicit consequence in terms of increased public pressure in stage 2 as shown in Figure 23. Also the issue development indicates the building up of opposing two fronts, with an offensive interest group, the DCA, on the one side and Nycomed and the DMA in the defensive position on the other side.

In relation to the gap analysis concept, the development of the issue to this point were contributing to widen the gap, as Nycomed stuck to its position that nothing were wrong with the product and at the same time new facts kept being placed on the agenda, and the DCA were successfully typecasting Nycomed as the “bad guy”. This is clearly illustrated throughout the case as the collaboration and support of stakeholders figuratively speaking were beginning to leave a sinking ship, leaving Nycomed as the vessel going under.

Looking at the diffusion curve the Letigen issue lifecycle in Figure 23, the development of facts, number of non-supportive stakeholder, media involvement in the issue in terms of number of media involved and coverage, indicates that the issue had in fact moved to stage 2 of the lifecycle thus

becoming a “potential” issue. Thus Nycomed could no longer use the offensive approach to solve the issue, but would still have the option of adapting a proactive strategy, and take action to avoid that the issue would develop further into the current and crisis stage.



According to Winter & Steger’s framework for analysing and forecasting external pressure on organisations, the combined pressure made up from facts, stakeholder awareness and media coverage, which characterised the Letigen issue in stage 2 was clearly increasing. The number of cases that the DCA collected exploded and Nycomed became more and more isolated in its standpoint (that there was nothing wrong with Letigen).

Figure 24 - Key events and statements in Stage 2 – Emerging issue

August 2002

06/08-2002. DCA's magazine brings three pages on the Letigen issue. The number of incidents reported on serious adverse effects caused by Letigen is now nine. Arne Astrup states that the product should undergo new and more extensive tests as a condition for continued sale of the product. (Tænk og Test, issue 28, August 2002)

09/08-2002. Danish Medicines Agency sends out a press release concerning Letigen. They state that the adverse effects are well documented and can be explained. In total there has only been 124 reports of adverse effects caused by Letigen, despite that more than 750.000 people have been treated with the product. The connection between Letigen and Randis Vasculitis is subdued and vasculitis is considered as almost impossible to foresee. Arne Astrup states that Letigen should continue to be sold on the market but be reserved to fewer patients.

31/08-2002. Ekstra Bladet brings a story on Doctor Bjørn Richelsen (vice-president of Danish Nutrition Council) who states that he under no conditions could see any reason for prescribing Letigen to his patients.

September 2002

01/09-2002. Ekstra Bladet documents that overweight children are involuntary guinea-pigs for Letigen. Arne Astrup believes that Nycomed receives special treatment from the Danish Medicines Agency. In their editorial, Ekstra Bladet back up the request for withdrawing Letigen from the market while it is thoroughly examined.

02/09-2002. The Danish Medicines Agency sends out a new press release about Letigen, which is a bit more critical than the previous. In the release, the agency warns about serious adverse effects that are not mentioned in the product resume, e.g. coronary thrombosis and depression.

03/09-2002. Ekstra Bladet brings Swedish warnings against Letigen. The Danish minister of health, Lars Løkke Rasmussen, states that the Letigen case is not a political issue and that he is fully confident with the Danish Medicines Agency's dispositions.

04/09-2002. The DCA has now received 86 reports concerning unexplainable and often serious illness from people who have used Letigen.

07/09-2002. Ekstra Bladet unveils that between 400 and 500 children in the age 10-14 of years since 1997 have been prescribed Letigen. This is in despite of the former 18 years-old limit that is now reduced to 15 year. Ekstra Bladet and DCA have waited a long time to gain access to the documents of the case. The DCA has now received more than 100 complaints concerning Letigen.

12/09-2002. Ekstra Bladet states that it is impossible to ban Letigen in practice. There is not enough information about adverse effects. The reason is that Letigen is not sold in other countries that Nycomed deny that there are any problems with Letigen and that the reporting systems for adverse side effects are staggering behind and not working

13/09-2002. Socialistisk Folkeparti Send out a press release, stating that they will raise the issue in the parliament.

30/09-2002. There is now established a political majority for banning Letigen. TV2 documents that the Danish Medicines Agency as early as eight years ago knew that Letigen could cause coronary thrombosis in otherwise healthy people. Danish Medicines Agency has no explanation to why this information is left out from the label, and at same time believes that it is not necessary.

Source: www.slankogsyg.dk

6.1 Stakeholder mapping stage 2

From the Letigen issue lifecycle framework it can be seen that as the issue travelled through the lifecycle into stage 2, more and more stakeholders got involved and two fronts began emerging. The stakeholder development in stage 2 was an indication to the fact that the issue most certainly would not fade away again, as it had done previously. Therefore, after a relatively quiet August 2002, the stakeholder development in September began to pose new threats to Nycomed as supportive stakeholders shifted position to the issue and new stakeholders entered the arena. Also the entrance of politicians to the stakeholder map marked the beginning politicization of the issue. The following will describe the stakeholder development in stage 2 according to their position to Nycomed and the Letigen issue.

Supportive stakeholders

The supportive stakeholder group consisted of the DMA and expert Arne Astrup. Both were categorized as mixed blessing stakeholders, but supportive in stage 1. Throughout the development in Stage 2, the DMA remained *supportive* to Nycomed, thus backing up on Nycomed's position to not withdrawing the product. More interestingly, expert Arne Astrup at first remained supportive (in August 2002) stating that the Letigen should stay on the market, but undergo new clinical test, for then later suddenly to shift position to non-supportive, claiming that Nycomed received special treatment from the DMA. This sudden shift of positions left Nycomed with one supportive stakeholder. The DMA as a mixed-blessing stakeholder, but supportive stance to the Letigen issue left Nycomed with an ally with both a high potential for corporation, but also a high potential for threat if the DMA should change position, due to public or political pressure.

Non-supportive stakeholders

The red arrows in the Letigen issue lifecycle analysis indicate non-supportive stakeholder involvement in the issue. The DCA and the media were they main drivers behind the development in stage 2. A Nycomed representative described the non-supportive stakeholders' role as such: *"the media just followed it – they always do. So the media didn't push it. There is no doubt that the DCA and Tænk and Test pushed the issue very hard"* (Interview Nycomed 2003). The following part will map the non-supportive stakeholders in stage 2.

Experts / Doctors

A new expert joined the opposing coalition. Doctor Bjørn Richelsen, vice-president of the Danish Nutrition Council, entered the debate and stated in Ekstra Bladet that he as a doctor under no circumstances would prescribe Letigen to his patients. Together with Arne Astrup, the DCA now had two experts supporting their case and helping them to position the DCA's case against Nycomed.

The DCA

The DCA continued to build up their case against Nycomed during the summer of 2002, and in September 2002, they entered the media debate again providing new facts on adverse side effects from using Letigen. Up to mid September 2002, the DCA had collected more than 100 cases where people had suffered from serious adverse side effects. A conjecture for why the issue was pushed so hard by the DCA, was explained by a Nycomed representative when discussing the DCA's interest in the issue: *"if you look at the Danish Consumer Association, Forbrugerinformation and Forbrugerstyrelsen and how those organizations have developed over the last five years, many things have happened and they strongly need to position themselves as being the consumers' spokespersons. Something happened and last year was the time where they felt that it was right time to explore this case. That is not so surprising if you look at their history. It could have been next year or in two years. It was more or less obvious that it should happen and this was a good case for them"* (interview with Nycomed 2003).

The Media

The media continued to follow the case, with Ekstra Bladet in the lead. With only a few published stories in August 2002, the coverage of the case intensified in September 2002 where several of the larger newspapers as well as both TV2 Nyheder and DR Nyheder joined in.

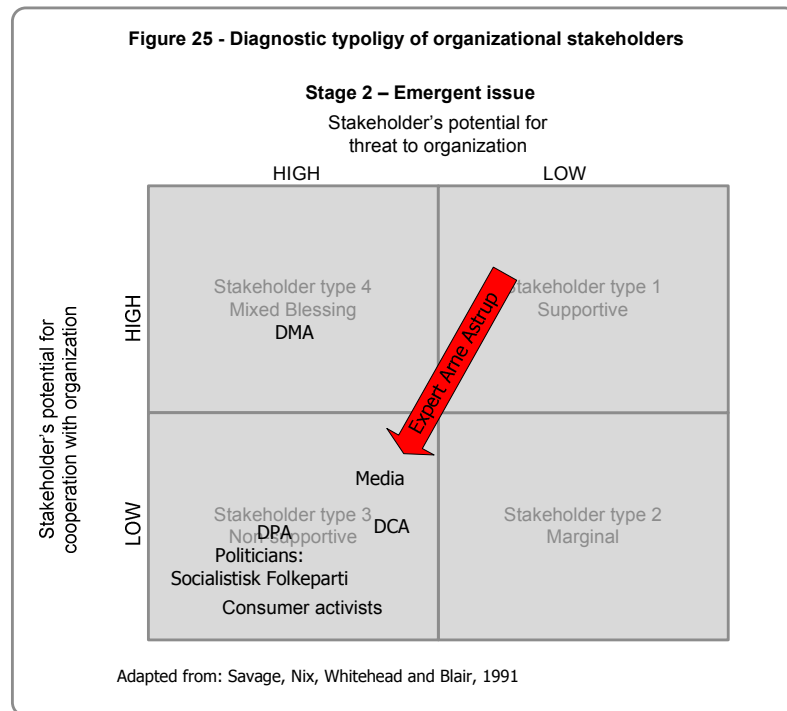
Politicians

One of the most important indicators to that the issue could take off and develop into stage 3 of the lifecycle, the current and crisis stage was the entrance of politicians to the debate. The Danish left wing party, Socialistisk Folkeparti (hereafter SF), picked up the issue, stating in the media that they would take the case to Folketinget's health committee and demand political intervention. With a

high degree of threat to Nycomed and a low potential for cooperation, SF entered the stakeholder map as a non-supportive stakeholder.

The DPA

The DPA did not contribute to the development in Stage 2, but was still an influential factor to include in the stakeholder map. This leaves with the following stakeholder map for Stage 2 in figure 25 below.



6.2 The issues management process - stage 2

Having already established that Nycomed did not follow the issues management framework in Stage 1, as a consequence of not having a formalized system set up to conduct this, the following part will examine what Nycomed did do in stage 2 and what went wrong. *“The process of mediation is critical and has the effect of accelerating the full development of the issue. It is therefore essential that companies which are targeted conduct regular and effective monitoring of the commercial, regulatory and social environment in order to identify stage 2 issues and begin to formulate action plans to deal with them”* (Regester & Larkin 1998:51).

6.3 Response strategy - stage 2

According to the theoretical framework Nycomed could adapt a proactive strategy to resolve the issue in stage 2. This is supported by Regester & Larkin in the following statement: *“At this stage [Stage 2] of the issue’s development it is still relatively easy for the organization to intervene and play a proactive role in preventing or exploiting the evolution of the issue”* (1998:51). Taking Nycomed’s responses to the allegations into consideration and their continued defensive stance to the issue that nothing was wrong with the product, Nycomed’s response strategies were reactive. Instead of proactively influencing the debate and the issue development, Nycomed were constantly responding to the allegations every time new facts were presented. Thus every time something new surfaced, they responded to it by communication to the authorities and the media that they stuck to their position on the issue. In relation to the gap analysis concept (figure 22, p.59), there was no indication that Nycomed had changed their perception of the issue as a pure communications problem. Nycomed basically continued to treat the issue as a perception problem that could be fixed by the continuous communication that nothing was wrong with the product and that the alternative was worse if the product was taken off the market, due to the fact that it was an approved drug and many people had used it without side effects and, as with all types of medications, a small group of people will potentially experience side effects

“The choice of an approach that is workable and is likely to succeed, is greatly influenced by the degree of importance the public attaches to an issue and the degree of credibility which an organisation enjoys in the public’s eye when speaking on that issue.” (Bartha, 1995) The above statement by Bartha was the problem in a nutshell for Nycomed, in the sense that the Letigen debate seemed to have had a high degree of importance to the public (measured on media exposure), and the traditional “David versus Goliath-battle” which the issue was turning into, i.e. the people who got severely ill by using Letigen versus the big profit-oriented pharmaceutical company, gave Nycomed a very low credibility, and difficulty in getting their message across that there was nothing wrong with the product.

Another conjecture to why Nycomed conducted a seemingly reactive strategy in this early stage was that the stakes were high for Nycomed. Management knew that if the Letigen was pulled from the market, chances for a reintroduction were low. Some of the product ingredients were already

banned in the USA and in the rest of the EU. More importantly, the costs involved in new testing at the scale demanded by the DMA, after today's standards, would be too high in relation to the actual revenues of the product. Another risk for Nycomed, as stated by the CEO, was that if the product was taken off the market, chances were that a competitor could enter with new product and take the dominant position within one or two years.

Finally, due to the fact that Nycomed did not have an issues management focus in the company, a conjecture would be that the cost-benefit considerations and implications were decisive to their response and maybe also due to the fact that the product performance had not yet been affected by the campaigning of the non-supportive stakeholders. In other words, Nycomed's motivation to proactively try to solve the issue, for instance by restricting the patient target group or recall the product was low.

Therefore, Nycomed's response strategy was more characterized as a reactive and defensive "fight all the way" approach to respond to the increasing amount of allegations made against them. When a new case or facts would be presented by the DCA or the media, Nycomed would subsequently deny responsibility and state that it could not be related to Letigen and that nothing was wrong with the product. According to the theoretical framework the direct consequence of conducting a reactive approach (reactive as opposed to being proactive in stage 2) is that the focal company, in this case Nycomed, loses control over the issue and it is up to others to secure resolution. But for Nycomed, the survival of Letigen was more critical than the bad media exposure that followed and the duration of the crisis.

According to Savage et al's framework for stakeholder strategies, Nycomed should conduct a defensive strategy towards non-supportive stakeholders because of their power and ability to influence the development of the issue. In an issues management context, just as the reactive strategy is an option when the issue is in the current and crisis state, the defensive stakeholder strategy should also be, according to Denise Deegan, postponed to this stage, "*as a dialogue approach can be recommended as a more successful way to deal with issues than just fighting and ignoring powerful pressure groups*" (Deegan 2001:22). But in stage 2 Nycomed did conduct a defensive strategy towards the non-supportive stakeholders which came to expression by questioning the credibility of the Letigen "victims" in the media, as belonging to a high risk group

of overweight patients that already suffered from health issues caused by their lifestyles and obesity. In order to leverage the pressure, Nycomed continued to conduct an “*involving*” strategy towards the DMA throughout stage 2, i.e. informing them on the issue development and their approach to handle the issue. But as the issue got closer to developing into stage 3, the DMA was also becoming under pressure to intervene and resolve the issue in favour of the non-supportive stakeholders.

6.4 Sum up stage 2

During the course of stage 2 Nycomed did not find a way to manage and contain the issue and prevent the Letigen issue developing further to the current and crisis stage. Several factors had their influence on this.

First, According to the lifecycle analysis framework Nycomed had the option to choose the proactive response strategy in stage 2 to find resolution to the Letigen issue. The premise for this would imply, as already discussed in stage 1, that the company had analysed the situation as the issues management process prescribes. The aim of conducting a proactive response strategy would be to close the expectational gap, which at this stage of development was beginning to expand. As the issue was still seen to be a strategic-operating problem, as perceived by the non-supportive stakeholders Nycomed should choose the appropriate strategy to close the gap. As the underlying notion for the proactive response strategy is that companies should only conduct change strategies in order to meet stakeholder expectations, nothing more, the dialogue strategy towards the non-supportive stakeholders would be necessary in order to identify and meet the actual expectations of those.

Second, Nycomed did still not identify that they were dealing with a strategic operating issue (or refused to realize this fact), which ultimately limited their possibility to close the expectational gap between Nycomed and the involved non-supportive stakeholders. The approach to handle the issue as a pure communications gap that should be closed, by changing stakeholders perceptions of the issue backfired, and instead put fuel to the fire and widening the expectational gap. Also by not approaching the gap as a strategic-operating problem, Nycomed also limited themselves from choosing the proactive response strategy in order to resolve the issue, thus, as the issue developed through stage 2, the opposing coalition of non-supportive stakeholders increased in strength and

number and thereby increased the overall pressure against Nycomed, moving the issue to stage 3, with the consequence of limiting Nycomed's response options to the Letigen issue further.

Third, product performance had not yet begun to suffer from the increased public awareness and negative publicity, and as a consequence, I conjectured, the motivation for Nycomed to proactively respond to the issue was very low. If Nycomed recalled the product it would very difficult to reintroduce to the Danish market and would leave ground for the entrance of new competing products.

Finally, by taking on the defensive approach towards the non-supportive stakeholders in the early stages of the lifecycle (both stage 1 and 2), Nycomed failed to reach a solution that could work for both parts. This resulted in an even harder campaigning from the DCA as they succeeded in collecting facts and evidence to strengthen the case against Nycomed as well as drawing new and powerful stakeholders into the arena, i.e. politicians who were actively advocating for a political majority to vote for intervention to ban Letigen from the Danish market.

After two months where the stakeholders involved in the issue gradually increased the pressure on Nycomed, the Letigen issue was catapulted into stage 3, the current and crisis stage described in the next section.

7. The Letigen issue lifecycle stage 3

“In the current phase, the issue has matured and is displaying its full potential upon those involved. It becomes very difficult to affect the issue as it has now become enduring, pervasive and increasing in its intensity. The different parties involved recognize its full importance and in response, place pressure on regulatory authorities to become involved” (Reger & Larkin 1998:52).

Just as the theory describes an issue’s development in stage 3, the current and crisis phase, the Letigen issue was developing into crisis. I have chosen to mark the point where change took place from current issue to crisis issue between October and November 2002. Reger & Larkin has described the change in stage 3 in the lifecycle framework as *“in no time at all the issue ramps up from current to crisis to reach a formal institution such as a regulatory authority which has the power to intervene or impose constraints [...] as a way to resolve the situation” (Reger & Larkin 1998:53).* Just as in theory, the issue in stage 3 was developing fast into crisis, with a broad range of non-supportive stakeholders demanding Nycomed to withdraw Letigen from the market, and if not, calling for political intervention.

Following the gap analysis concept, the gap was now perceived by the majority of stakeholders as a strategic operating problem for Nycomed and the size of the gap had now developed to be relatively large measured in terms of the amount of external pressure Nycomed were facing. In the general picture held by the public the only legitimate solution to issue was an intervention from government authorities, as Nycomed seemed to hold on to their stance on the issue. Going through the key events in stage 3 - current issue in figure 26 A+B, several signs stood out that the issue was turning into crisis. Representatives of two political parties in Folketinget were demanding intervention from the Danish Health Minister, the media coverage exploded and new facts and stories on Letigen and side effects were increasing on a weekly basis. A Nycomed representative described the situation as *“It was surprising and it seemed like there was a new thing every day. Every time we tried to get a hold of the issue, something new would turn up. It was like a dragon with many heads. For example, the politicians would get involved or there would be something new from the consumer association, or the pharmacists association would have a go at us” (interview with Nycomed 2003).* An interpretation of the above statement indicates that Nycomed had lost control of the issue and were having increased difficulty in trying to control its further development.

Figure 26 A - Key events stage 3 – current issue

October 2002

01/10-2002. Ekstra Bladet reveals that only a few persons participated in the product testing that preceded the final approval of the Letigen in 1990. Bjørn Richelsen states that Nycomed should start all over in their clinical tests of the product. Also Tænk+Test (DCA member magazine) publish a very encompassing article in their October issue, with lots of background information and documentation. The number of reports to the DCA has now risen to 107.

02/10-2002. Ekstra Bladet prints an article telling about four deaths where Letigen is suspected to be a contributory factor. The daily newspapers Politiken and Information have picked up the issue.

05/10-2002. The Danish Medicines Agency sends out a press release stating that Letigen will now be subject to special surveillance. DCA stands by their claim, as previously, that this is not sufficient and that Letigen should be withdrawn from the market and be examined a lot more thoroughly.

06/10-2002. DR1's Sunday magazine drill down in the Letigen case. While dietary medicines such as Letigen were banned in 1999 in the rest of the EU, the Danish Medicines Agency approved the continued sales of Letigen in Denmark. The responsible person who approved the drug in the DMA had worked for Nycomed previously and a few days after the approval of Letigen he signed a new work contract with Nycomed.

08/10-2002. The DMA states to Dagbladet Information that the media has run amuck over one single incident and that the number of Letigen incidents is not nearly as bad as portrayed in the media, considering that the product has been used for more than 12 years.

10/10-2002. Dagbladet Information reveals that the number of possible Letigen-related deaths now has doubled since the DMA's latest approval of Letigen in the spring of 2002. Nycomed's CEO states to Dagbladet Børsen that the sales of Letigen is down to half and is that the whole issue is based on an emotional 'media storm'. According to Nycomed there has only been one death that with certainty can be related to Letigen and that was a suicide.

11/10-2002. The number of reports given to the DCA is now up on 140. (www.fbr.dk 2002)

13/10-2002. The DCA and the DPA demand Letigen to be banned from the market. The Health minister was called in concert with four political parties that demanded an instant ban of Letigen. Nycomed's CEO expressed concern with the fact that more and more users of Letigen became concerned and he declared that he was proud of the product. The DMA stated that Letigen is a well documented drug with an acceptable profile of adverse effects. Nycomed reported that 980.000 Danes had used Letigen up to April 2002. (Politiken 13/10 2002)

Source: www.slankogsyg.dk

Adding to the escalating pressure against Nycomed, the DCA published their October issue of Tænk & Test with a focus story on Letigen, with comprehensive background information on the case. This marked the entry into stage 3 as the case story from the DCA was picked up more or less from the entire range of Danish national media. During the first two weeks of October 2002 the opposing coalition - now consisting of the DCA, expert Bjørn Richelsen, the media (led by Ekstra Bladet, Information, DR Nyheder and TV2 Nyheder), the activist consumers (former Letigen patients) and at least two political parties (Socialistisk Folkeparti and Dansk Folkeparti) - continued to build up the pressure. The DCA and the media kept finding new angles to the issue presenting new evidence and facts concerning adverse side effects from the use of Letigen and the politicians were beginning to exploit the growing concern in the general public and, just as with the DCA, to use the case for their own personal agendas. On the other side, Nycomed was still claiming that there was nothing wrong with the product. Nycomed produced new evidence that should document that the product was safe to use under the right conditions. The attempt to provide new facts

regarding the product did not help to close the gap and experts were quick to demine the evidence. As the DCA continued to get new reports on adverse side effects, their case seemed to strengthen on a daily basis. Another important factor in the development was the DMA's announcement that Letigen would be put under special surveillance – an indication to the fact that also the DMA was under heavy pressure to resolve the case.

Figure 26 B- Key events stage 3 – current issue - continued

15/10-2002. Torben Lund (Member of European parliament) wants to have Letigen withdrawn from the market as soon as possible and asks the EU Commission to look at the DMA's approval procedure for Letigen.

17/10-2002. Dagbladet Information reports that the number deaths that can be related to Letigen increases month by month and there now are 10 Letigen related deaths. The DMA's own list includes 7 possibly related deaths and they are knowledgeable of about 40 serious adverse effects. The DCA has finally gained access to the documents regarding the DMA's approval of Letigen and find it chocking that Letigen has been approved on such a loose foundation, 180 test persons on a period of 48 weeks. In spite of the doubling of serious adverse effects in just three months, the DMA and Nycomed stick to their claim that Letigen is not dangerous.

19/10-2002. Dagbladet Information gets the DMA to establish the exact number of unique Letigen users – not 980.000 but 509.000. Furthermore its documented that the DMA continues to be silent about the risk of the most serious adverse effects connected with the use of Letigen, and that not even coronary thrombosis and depression have been included on the product resume. The DMA stated that they choose not to mention coronary thrombosis and depression in the resume.

20/10-2002. The sales of Letigen take a vertical dive and the DMA sends out a press release explaining why the number of unique Letigen users now is only 509.000. The DMA also implicate the use of the older, undocumented, Helsingør-Pille in their basis for approving Letigen. Berlingske Tidende examines the correlation between number of users and cases of serious adverse effects. They state that on the basis of the new numbers of unique Letigen users, the number of adverse effects could be higher than assumed so far. The DCA calls the situation very alarming and two politicians back up them up.

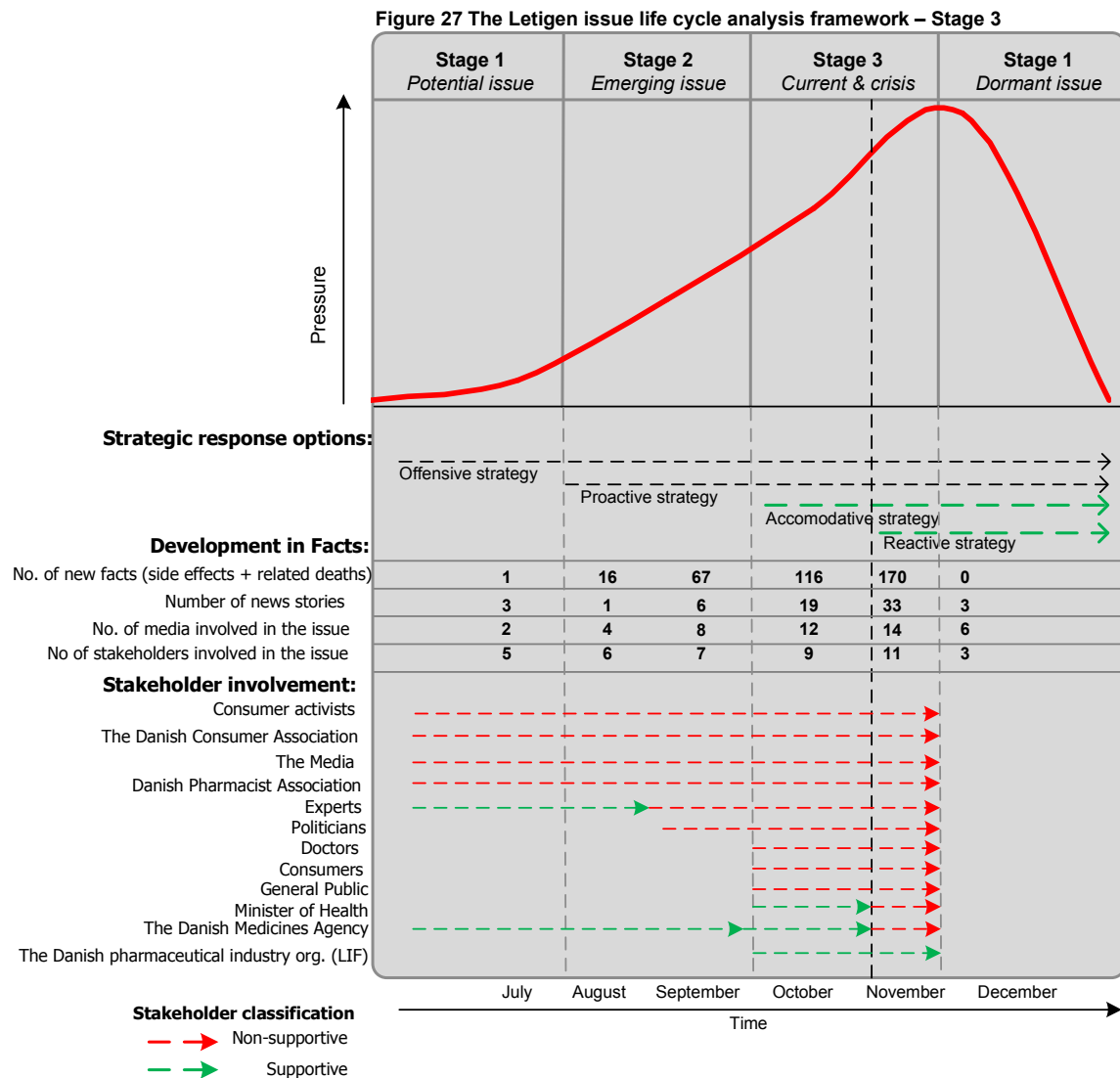
22/10-2002. The Pharmaceutical Industry Association (LIF) back the DMA up in a press release and warn about consumer interest groups and organizations, individuals or politicians disregard the DMA's judgments about the safety of a product.

23/10-2002. Dagbladet Politiken informs that there have now been reported 158 incidents with adverse effects caused by Letigen to the DMA. 41 of them are serious and among these are seven deaths connected to the use of Letigen.

Source: www.slankogsyg.dk

During the rest of October 2002, the issue continued to develop with an alarming strength and by the end of October all national media, print and broadcast, were covering the story. In addition, two political parties, a member of the European parliament, the DCA, the DPA, experts and general practitioners as well as consumers were involved and putting pressure on Nycomed. The only thing still keeping the balance was the continued support from the DMA and that Health Minister Lars Løkke Rasmussen refused to get involved in the case and that the pharmaceutical industry organisation LIF entered the debate giving some support to Nycomed. In an overall perspective, looking at the Letigen lifecycle analysis framework for stage 3 in figure 27 combined with the development in key events in stage 3, the process seemed self-perpetuating. The correlation between the increasing number of non-supportive stakeholders, presentation of new facts and

evidence against Letigen and increasing amount of negative publicity marked the point where the issue turned into crisis.



The model states a clear correlation between facts, i.e. number of serious illnesses and deaths potentially related to Letigen and the number of media involved in the debate as well as a correlation to the increasing number of stakeholders who were involved in the issue. In a theoretical perspective Nycomed's strategic options were now limited and consequences for a pharmaceutical company like Nycomed could be "demands for additional safety data through costly new patient trials, blacklisting of specific drugs restricting patient indications, major changes in prescribing information, company funded patient education programmes and ultimately, product withdrawal.

Options available to the organization to affect or influence the issue are now limited – it is in crisis response mode” (Regester & Larkin 1998:53).

Figure 28 - Key events Stage 3 – Crisis issue

November 2002

01/11-2002. Tænk+Test (DCA magazine) establish that Nycomed's Letigen examination concerning increased blood pressure is useless and bring the story about Jenni's doctors. According to Jenni's doctor, Nycomed was informed about the death. Both Ekstra Bladet and Dagbladet Information follow up on the case. Minister of Health, Lars Løkke Rasmussen, announces in TV2 Nyheder that there will be an increased control with doctors and drugs and an easier reporting of adverse side effects.

03/11-2002. TV2 News reveals that Letigen can cause diabetes and that Nycomed for years have had knowledge about a survey that shows that Letigen is not good for overweight people with diabetes. The DMA, with Jens Ersbøl, states that "it is probably not the most suitable idea to prescribe Letigen to people with diabetes or to people in risk of getting diabetes".

04/11-2002. TV2 News tells that a survey, paid by Nycomed, with the purpose of showing that Letigen does not affect blood pressure is worthless and that overweight persons with blood pressure problems should beware of Nycomed's documentation. DR TV-Avisen tells Jenni's story. Jenni died in 1995 and her parents were sure that the death was caused by Letigen. Jenni's doctors, who were on Nycomed's payroll, have for years denied to report the death to the DMA. Practicing doctors who make money by working for the pharmaceutical industry have no obligations to inform that to their patients.

06/11-2002. The Letigen case is discussed in Parliament, where the Health Minister is in an open consultation with the Health Commission.

11/11-2002. Dagbladet Information now engages Nycomed's new safety assessment regarding Letigen, which far from satisfies the DCA.

13/11-2002. Dagbladet Information has talked to senior statistician Jan Wohlfart from Statens Seruminstitut about Nycomed's new safety assessment of Letigen. Jan Wohlfart dismisses Nycomed's argumentation that there are no clear connections between the use Letigen and serious adverse effects such as cerebral hemorrhage and coronary thrombosis. The DCA and the DMA disagree on the treatment of reports of damages that could be caused by Letigen.

14/11-2002. Nycomed reject the critique to the latest safety report on Letigen. The registration board, under the DMA, recommends that Letigen is suspended.

15/11-2002. Nycomed stand by their claim that Letigen is a safe product.

21/11-2002. The DMA decide to suspend Letigen from the Danish Market until further evidence is provided from Nycomed regarding product safety and efficiency. Nycomed is uncomprehending about the decision.

Source: www.slankogsyg.dk

To sum up the issue development in stage 3 of the Letigen case, the lines were drawn up and the trenches were dug. On one side there was the coalition between the consumer organisation DCA and the media. Here the DCA was the aggressor and the media more or less just the messenger. On the other side were the government organisation DMA and Nycomed. Here the DMA was in the line of fire, due to its approval of the drug and their persistent defence of their previous actions and

decisions. They would not commit to have done anything wrong. Initially on the sideline were the politicians, the medical professionals (doctors), the pharmaceutical Industry Association and the Health Minister and his ministry. The balance between the two sides finally tipped over in favour of the DCA, when a few medical professionals joined the debate and in this sense influenced the politicians to participate in the debate. When the Minister of Health finally joined the debate, the scales tipped all the way over in favour of the DCA and the consumers.

7.1 Stakeholder mapping stage 3

The stakeholder development in stage 3 of the lifecycle was the leading factor to the increased pressure on Nycomed. In line with the emergence of an increasing amount of new facts and evidence of the harmful effects of using Letigen, the media gave easy access to non-supportive stakeholders to present their views to the general public, while Nycomed's position became increasingly unclear. According to a Nycomed representative this was *"basically to be expected because there hadn't been any outreach to these people / interest groups actively. And they were not sure of what Nycomed's position was; I don't think many people were"* (interview Nycomed 2003). In stage 3 basically all imaginable stakeholders were involved in the issue, and most of them advocating for a full product ban. Due to public pressure and the issues' stage in the lifecycle, Nycomed were now heading into crisis management mode. The following describes how the various stakeholders affected the issue development in stage 3.

Non-supportive

The Danish Consumer Association

The DCA continued to campaign hard against Nycomed. Both in October and November they published focus articles in Tænk & Test, presenting their collection of cases where people suffered from side effects. In both cases, the stories in Tænk & Test were instantly picked up by national media.

Consumers

Consumers (users of Letigen) were now getting more and more influenced by the massive media coverage, and began to stop buying Letigen (or doctors stopped prescribing it?) in the current phase the product were down 50 percent compared to normal and in the crisis phase, sales dropped 80

percent. An assumption would be that it was a combination of “consumers” that stopped using Letigen due to fear of adverse side effects and doctors that stopped prescribing the product due to the same fear.

Politicians

The issue started to be politicized already in stage 2, and as the issue developed it turned out to be a perfect case for politicians to get media coverage. Torben Lund, member of the European parliament stated that he would bring the case to the European council and politicians from several parties demanded intervention from the health minister.

Experts

“Experts” were frequently used by the media for statements to back up the stories on the risks of using Letigen making their claims credible. In stage 3, a broad range of experts were in play from several “credible” institutions, among others, Statens Serum Institut and the Danish Nutrition Council.

Doctors

When one of Nycomed’s most important stakeholder group joined the debate it had a strong influence on the issue development, even though the stakeholder group was only represented by a few professionals, a representative from Nycomed explained their role as the following: *“In fact the doctors also went into the discussion and it was picked up by the media. Even though their point of view was only represented by one or two doctors the politicians picked it up as the opinion of the whole medical profession”*.

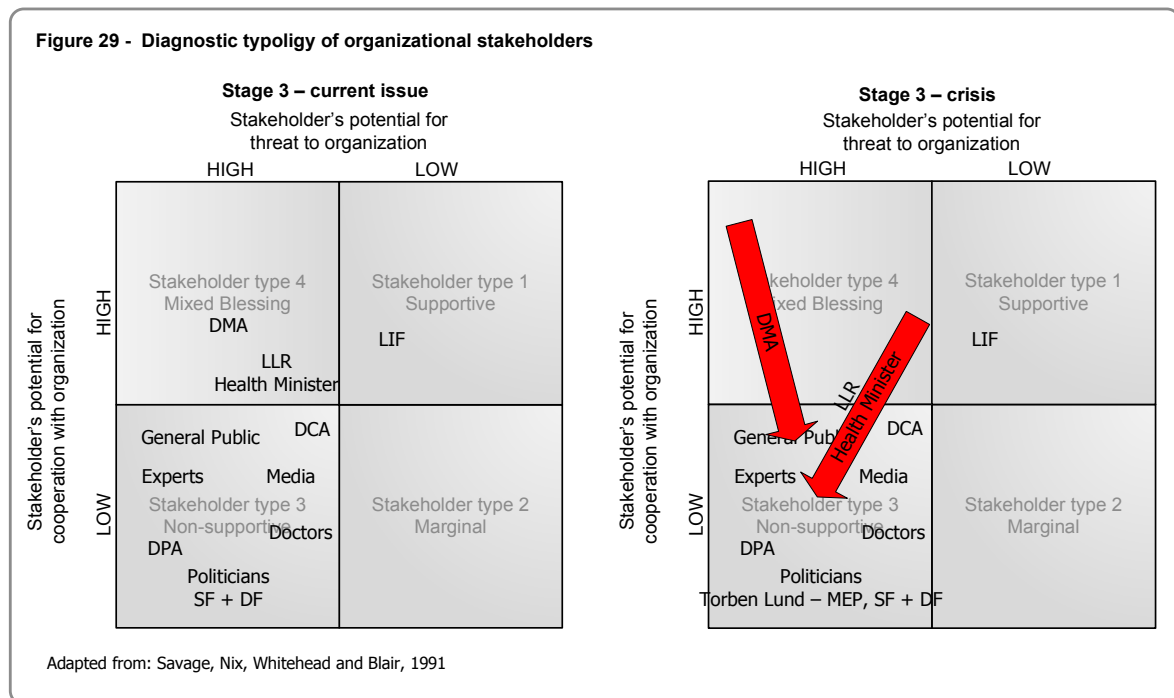
The DPA

The pharmacists association continued to have a voice in the debate and together with the DCA they demanded that Letigen should be pulled of the market.

The Media

The role of the media cannot be underestimated in relation to the issue development. The case had proven to be perfectly suited to media coverage, containing all there needs to be in order to create headlines. The further the issue developed Nycomed had increasing difficulty in getting their points

of view across. A Nycomed representative, Nycomed, described the media's role in the current and crisis stage as *"the media were not interested in our side of the story. It was impossible for us to have any dialogue with journalists, as they would interpret everything we communicated to make us look bad. In the end our only means of communication was for the Danish country manager, Bent Kjærsgaard, to do live interviews"* (Interview Nycomed 2003).



Supportive

The DMA

The DMA who had refused to bow to the demands from the media, politicians and the DCA became, like Nycomed, increasingly under pressure in stage 3 which resulted in first, that Letigen came under increased surveillance in the current phase and later due to political pressure (my assumption) in the crisis phase of stage 3 served the death blow to the product, ordering a full suspension of Letigen on the Danish market. Categorized as a mixed blessing stakeholder, this stakeholder type has the potential to be both supportive and non-supportive, with both a high potential for threat and support to the organization. Thus towards the end of the issue, the DMA was forced to intervene to resolve the issue, thereby shifting side to the opposing coalition. A Nycomed representative described the course of events that characterized Nycomed's cooperation with the

DMA like this *“there where the medical parties themselves, the ones responsible for medication protection and throughout 90 percent of the issue they were supportive, and then there was another (political) pressure on in the end and they stopped being supportive, and that was the interesting thing to watch. In the way that there was a broader issue at play in Denmark about who it is that decides on medication. Nycomed’s position throughout the issue was that it is the Danish medicines agency that decides. As that issue developed I noticed this slight shift in power, in terms of who is deciding this, politicians also started to get involved on pressure from the Consumer Association in Denmark though they are not allowed to, so there was a lot of new interest groups as well with a stake in the issue”* (interview Nycomed 2003).

LIF

The Pharmaceutical Industry Association (LIF) went into the debate backing up the Danish Medicines Agency up in a press release. Supporting Nycomed and the DMA, LIF was warning about the consequences of when consumer interest groups, organizations, individuals and politicians disregard the DMA’s judgments about the safety of a product.

Health Minister

The Danish Health Minister was forced to take a position to the issue in stage 3. Initially supportive to Nycomed and refused to take action to ban the product, stating that it was up to the Danish Medicines Agency to control pharmaceutical products on the market. In November the minister was under pressure from Folketinget and though he never officially intervened in the issue, a conjecture could be that the DMA’s sudden change in stance towards issue were they eventually decided to suspend the product on November 22nd, was due to his pressure. Taken the high public focus on the issue one could assume that it would also be in minister’s interest that the issue would be resolved.

7.2 The Issues Management Process – Stage 3

By the time an issue reaches stage 3 of the issue lifecycle there is in theory still an opportunity to prevent crisis, assuming that the issue develops in a linear process across the stages. As stated in the theoretical framework, not all issues progress accordingly, but can be speeded up. The development in this stage suggest that the Letigen issue suddenly took off in stage 3 and developed from current to crisis in a very short time span, thus limiting the options for strategic responses dramatically. The

communication strategy that Nycomed conducted did not seem to have an effect and the issue kept rolling.

In relation to the gap analysis framework Nycomed still tried to close the gap by means of communications vis-à-vis the involved stakeholders. A Nycomed representative explained their communication strategy as such: *We did a lot of communication to the medical profession, informing them about the situation, we did outreach to politicians - later – and we told them what the situation was – that was the politicians in power, we did communication to the pharmacists, we tried to have communication to the Consumer Association, so we were doing some of the right things, but too late [...] We also had meetings with the DCA, but it didn't change anything, their mission was also to raise the discussion on side effects, and they basically stated that they were going to use this case to profile themselves and they were going all the way with it” (Interview Nycomed 2003).*

The communication strategy did not seem to work and it and the messages Nycomed tried to get through basically drowned in the increasing amount of cases brought forward by the DCA and the media. Throughout the case, one could get the impression that Nycomed hardly participated in the debate and hardly communicated with its key primary stakeholders. But that is incorrect. Nycomed representatives have informed that their communication to the medical professionals, to the pharmacists, to the opposition (DCA), the politicians, and to the media was continuous and substantial, but just too late. Their message was the same throughout the issue, that the product was safe and that the DMA considered the product safe. To this a Nycomed representative explained: *“We had regular interviews with journalists and TV journalists, saying the same thing which was our position which is that the product is safe and the medicines agency thought the product was fine. So one of the impressions you could have that Nycomed didn't communicate with the media was not true, we did communicate, they just weren't interested in our position”.* This statement underpins the Nycomed's continued refusal to identify the Letigen issue as a strategic performance problem. While Nycomed kept communicating to influence perceptions, the non-supportive stakeholders' demands and expectations were that Nycomed should, willingly or not, remove the product from the market.

7.3 Nycomed Response strategy – Stage 3

The following part will analyse and describe Nycomed's issue response and stakeholder strategies in stage 3, in relation to the theoretical framework. The consequences of Nycomed's response so far was that the option to conduct offensive and proactive strategies to regain control of the issue had passed and the further the issue went through the life-cycle the less room for manoeuvre was left for management to reach a favourable outcome. According to the framework presented in figure 27, two strategic options are available for companies in stage 3. Because Nycomed reacted on the issue at this late in the lifecycle, unable to close the gap and resolve the issue, they now had two strategic options left: the accommodative and reactive strategy. The first strategic option would be to concur with the pressure from the DCA, the media and the rising pressure from regulatory authorities. In Nycomed's point of view, there was nothing wrong with the product and they were not about to give in to the pressure from the opposing coalition of non-supportive stakeholders. A Nycomed representative explained why the accommodative strategy was not an option: *"Listen; if we should withdraw products every time we had an issue coming, I tell you, we wouldn't have any products left. Getting issues is really a daily or weekly thing. We are living on people's diseases, and you have to be aware that in this industry there will be issues."* The second strategic response left for Nycomed is the situation described by Chase and Jones, where companies remain inactive until the issue reaches the crisis stage and chooses a reactive response to fight against any regulation or intervention posed by authorities to resolve the issue (Chase & Jones).

As the continuous communication from the CEO of Nycomed throughout the entire Letigen debate showed, the company did not think that there was anything wrong with the drug, they had not done anything wrong, and right to the end they were totally surprised by the DMA's decision to suspend the drug. In this sense Nycomed followed a reactive strategy, in their decision to *"fight all the way"* to keep Letigen on the market. In order to deal with these various non-supportive stakeholders Nycomed chose a reactive and defensive approach or strategy. Comparing this to the issue lifecycle model where I have shown that the reactive and defensive strategies are usually adopted when crisis occur.

Bartha states that: *"To be effective, organisations must act and communicate from a position of strength, which is found in the organisation's credibility"*. (Bartha, 1995) Nycomed lost its strength

when its credibility was put to the test in relation to the medical professions credibility, because who was to blame for the Letigen illness cases? Nycomed sold Letigen through the professionals, i.e. the doctors prescribing the drug to their patients. Nycomed could not blame the doctors for prescribing the drug to the wrong patients, because Nycomed was dependant on the doctors and their prescriptions. The users trusted their doctors and blamed the producer of the drug, i.e. Nycomed. To this dilemma, a Nycomed representative stated: *“We should have addressed the problem that some doctors were prescribing Letigen to the wrong target group earlier. [...] But even more important – had we addressed this discussion or problem we also indirectly would accuse a really important stakeholder group – namely the doctors. General practitioners do not like to be told by a pharmaceutical company that they are doing something wrong.”*

Nycomed tried to deal with the above dilemma in a different way, i.e. outside the media debate. Nycomed communicated directly to the medical professionals, and although some of the professionals themselves joined the debate in the media against the company, Nycomed considered this non-public communication strategy as the most effective, even though Nycomed wished for a stronger alliance with the doctors than was actually the case. In this sense, Nycomed was caught between a rock and a hard place. They couldn't put the blame where it was the most appropriate, i.e. with the doctors, and they couldn't publicly announce that their only source of bringing their product to the end-user was the problem. Nycomed could not tell the media that the professionals were not doing their jobs right by prescribing the drug to people who were not seriously overweight and thereby threatened by other deadly disease or death by obesity.

“An organisation stands the best chance of effectively relating to its intended audience when its message deals with an issue for which both the public interest and the organisation's credibility are at high levels” (Bartha, 1995:5). In relation to this, a further concern for Nycomed was that the media would have interpreted the message as Nycomed putting all the blame on the doctors. And in this sense the credibility of Nycomed as a representative of the pharmaceutical industry would in the public view have been considerably lower than the credibility of the entire medical profession. As Bartha puts it: *“The real danger occurs when the public is greatly interested in an issue. Any positioning attempt by a low-credibility organisation is likely to be counterproductive.”* (Bartha, 1995:6).

7.4 Sum up – Stage 3

All the connected course of events and decisions that has characterised the evolution of the issue combined with the fact that Nycomed was not able to contain the issue in the early stages led to the sudden increase in pressure that moved the issue first into the current stage and then into crisis. The public awareness on the issue included almost all possible stakeholders in Nycomed's external environment, from the general public to the involvement from key legislators in Folketinget. Ultimately the negative publicity not only affected the sales of the Letigen dramatically, dropping 86 percent¹, but the pressure also forced the Danish Medicines Agency to suspend Letigen, until Nycomed could produce new up-to-date documentation of the product. The negative publicity and the DMA's demands, which as already stated in Stage 2 would be too costly to produce, basically killed the product. This goes hand in hand with the issue lifecycle theory, which states that "once an issue has run the full course of its lifecycle, it will reach a height of pressure that forces an organization to accept it unconditionally" (Register & Larking 1998:54)

Just as in the previous stages, several factors contributed to the development to the suspension of Letigen. First, I conjecture that when the issue reached stage 3 Nycomed realized that they were now facing a strategic operating problem that according to gap analysis model could only be fixed either by a change in communication strategies or a change in operations in order to close the expectational gap (i.e. change the expectations of the non-supportive stakeholders to align them with the actual performance of the company). As Nycomed had no intention to willingly withdraw the product from the Danish market, they also limited themselves to one of the two strategic options available to find resolution to the issue, namely the reactive strategy. By taking this approach Nycomed fought to the end to keep the product on the market, but in terms of government intervention, this strategy implies that the solution is basically up to regulatory authorities to find a solution to the problem.

The next decisive factor to take into account in this stage is the political involvement from several parties in the Danish Folketinget. The Letigen case attracted political attention because, as with the activist group campaign, the issue was well suited for politicians to profile themselves to the public. Again, following the logic behind the issue lifecycle, when the public's expectations became

¹ Information, 14. November 2002

politicized and the issue was picked up in the governmental arena, Nycomed's strategic options to resolve the issue themselves decreased dramatically. Concerning the overall stakeholder strategy, Nycomed did try to get into dialogue with the leading non-supportive stakeholders in the beginning of stage 3, but at that point in time it was too late. The DCA had a good case and were determined to see Letigen to be taken off the market.

An interesting factor to take into account, as to why Nycomed did not react on this until the beginning of stage 3, was that sales had not yet been affected. This reflects the approach expressed in the earlier stages in the lifecycle that the issue were expected to disappear again, but when sales began to drop, Nycomed management was forced to resolve the case. Thus the sales and profit focus can also in this stage be assumed to play an important part as to what Nycomed saw as possible solutions to the issue.

Finally, to conclude what went wrong in stage 3, the chosen reactive response strategy option turned out to be unsuccessful. Nycomed were not able to get through to the media communicating *their* view on the issue, that the alternative would be worse if Letigen was taken off the market, and thus they were not able to influence and align either stakeholder perceptions or expectations to the actual performance of the Nycomed. Instead, Nycomed was left with a tarnished image and a suspended product. To recap on stage 3, the issue had now peaked and resolution was found by government authorities that decided to suspend the product. This leaves us with the final stage of the issue lifecycle, stage 4 "Dormant" issue.

8. The Letigen issue lifecycle stage 4

With the decision to suspend the Letigen from the market the DMA officially put an end to the issue. The large coalition of non-supportive stakeholders led by the DCA was successful in their campaign against Nycomed that peaked when the issue found resolution in Stage 3. Recapturing the Letigen issues lifecycle model for stage 3 (page 73) it can be seen that DCA stopped producing new facts, i.e. they reached their goal and the media coverage decreased during December to consist only of a few follow up stories. The product was taken off the market and the battle was over. Nycomed still had the option to continue to fight the decision made by the DMA, but Nycomed, as later quoted in the media by the Danish country manager, did not see it as an option to try to produce new product testing and to apply for a new license for Letigen because the reputation of the product had been damaged to a degree that it would be virtually impossible to reintroduce it to the market.

An interesting note to the fact that dormant issues sometimes have the possibility to resurface is that in the writing hour of this thesis (July 2008), a front page article in Berlingske Tidende covered the increasing use of dietary medicine in Denmark and the possible harmful consequences of this, which was experienced with the Letigen product *“that was suspended from the Danish market of several allegations of related deaths and harmful side effects”* (Berlingske Tidende, 21-07-2008:1)

This concludes the Letigen lifecycle analysis and the results from the stage analysis will be summed up in the following conclusion.

9. Conclusion

The following part will conclude on the key findings made in the stage analysis on what went wrong and what could have been done differently in Nycomed's handling of the case, seen from an issues management perspective. The following statement from a Nycomed representative sums it up *"Officially or externally too little was done too late and that is maybe one of the reasons why the issue took off and exploded last year."* (Interview with Nycomed 2003)

According to the issues management framework Nycomed did not have the focus on its external environment that is needed in order to identify, monitor, evaluate and plan proper responses to issues before they get the potential to develop into threats to corporate performance. As concluded in stage 1, this was partly due to the fact that Nycomed did not have an issues management approach or system in place at the time of the Letigen crisis. A strategic approach to the issue identification and analysis could have the following impact on the development at this stage. First, by using the *company issue checklist*, asking themselves the eight questions proposed in the framework, the Letigen issue could have been identified already in its early stage that they were dealing with an issue that might become strong enough to be a threat to the company. Second, by conducting a gap analysis in order to identify the real problem, whether they were dealing with a perception problem or strategic-operating problem, could have changed the course of events. If the issue was considered to have the potential to become a strategic operating problem already in stage 1, Nycomed could have chosen to try to close the gap in the first stage by conducting an offensive strategy to align stakeholder expectations to the actual performance of the company. Nycomed did not do that, and instead saw the issue as a pure perception problem and tried to solve the emergent issue by simply communicating that there was nothing wrong with the product.

Another crucial step in the issues management process that Nycomed failed to do in stage 1 was to identify stakeholders that was or could become involved in the issue. The theoretical frame proposes that some issues have the potential to become activist issues, and that these issues pose the greatest threat to performance. By using the *Issue Activist Checklist* analysis the result would have concluded that the issue was very suitable to be picked up by activist groups because of the issue characteristics. As a direct consequence of not getting the type of issue right in the gap analysis, Nycomed also failed to get the stakeholder identification right, which made them miss the opportunity to try to get into dialogue with the key stakeholders involved in the issue before it

would develop further in the issue lifecycle. These factors combined made the issue develop into stage 2.

Just as the lifecycle model prescribes strong issues that are not contained at the early stage of the lifecycle, will develop further and pressure will increase on the company. During stage 2, Nycomed did still not manage to get control of the issue. The Letigen issue was still not perceived to be a strategic operating problem vis-à-vis the expectations of the non-supportive stakeholders who were now driving the issue to the forefront of public attention. Nycomed still approached the gap between them and the involved stakeholders a misperception of facts that could be fixed by communicating that there was nothing wrong with the product. This approach backfired and instead widened the gap, as the common view among the non-supportive stakeholders was that there was something wrong with the product and Nycomed should remove it from the market. By not approaching the issue as a strategic operating problem, Nycomed also limited themselves from conducting a proactive strategy that according to the theoretical framework could have closed the gap in stage 2 and thereby securing the issue from developing into crisis.

The defensive stakeholder strategy that Nycomed had chosen so far to deal with the non-supportive stakeholders also seemed not to work. As proposed in the theoretical framework it is often more beneficial to try the dialogue approach in the early stages of the lifecycle to try to find a common solution to an issue that would work for all parts involved. The result of this strategy was that the key non-supportive stakeholders pushed even harder on the issue and was able to build an increasingly larger coalition of non-supportive stakeholder that eventually in stage 3, drew the issue into the political arena.

Nycomed came to experience a dramatic increase in pressure against them, with a large coalition of non-supportive stakeholders who wanted Letigen removed from the market. In concordance with increased negative public awareness, sales of the Letigen pill had also dropped dramatically. These two factors combined made Nycomed realize that the gap they were dealing with was a strategic operating problem. The consequence for Nycomed, if they pulled the product from the market, would be that a future reintroduction of the product would be too costly in terms of new product testing and second that competitors could enter the market for prescription dietary products. Thus in order to close the gap, Nycomed tried to solve the issue by getting into dialogue with virtually all

the involved non-supportive stakeholders, at this point in the lifecycle it was too late. According to the Letigen lifecycle framework, Nycomed had to strategic response options in stage 3 and chose the reactive strategy, under which the basic notion is to fight all the way against any intervention posed by governmental authorities to find resolution to the issue. The reactive strategy was in this case ineffective because the overall public pressure that at the end of stage 3 included all possible stakeholders, from customers to politicians forced the key government institution the Danish Medicines Agency to suspend Letigen from the market on November 21st 2002.

By analysing the case from an issues management perspective, it was clear that Nycomed did not have a systematic approach to effectively analyse and deal with potential issues in their external environment. The following sums up the main contributing factors to what went wrong in Nycomed's handling of the Letigen case.

- Nycomed did not identify the Letigen issue as a major threat in the first stages in Letigen's issue lifecycle
- The company failed to identify the issue's potential for being picked up by activist groups and misjudged on the key activist group's ability to drive the issue to forefront of the public agenda
- Nycomed misunderstood the nature of the gap behind the issue and therefore the identification of the issue as a strategic-operating problem as perceived by the key non-supportive stakeholders.
- The choice of overall reactive and defensive response strategies proved to be the wrong approach to handle the issue.

Based it on the above factors it can be concluded that Nycomed did not follow an issues management approach and that such an approach could have given Nycomed the window of opportunity to engage in strategies that would prevent the issue from reaching the public agenda and the product from becoming subject to government intervention

10. Perspectives

During the study of the Letigen case a number of interesting questions surfaced that could be interesting to deal with in relation to issues management and the practical application of the ideas presented in the thesis.

The analysis framework presented in this thesis proved its functionality as to analyse the development of an issue and to identify the different strategic options available to companies at each stage of the lifecycle. What the model did not take into account was the cost-benefit considerations that would facilitate decision making process to make the right choice: When and how to act. The prescriptive nature of the issues management process which suggests that companies should engage in conducting environmental scanning, prioritisation between issues that potentially could harm the company's product, reputation and ultimately the bottom line, in real life, who should actually do that? For a company like Nycomed, operating in more than 16 countries, with more than 500 different products and thus 500 potential product safety issues - the task would seem enormous. Who should perform the issues management, which issue should receive management attention and early action? The theory makes the process sound simple, but in real life it seems more complicated than that. Also it raises the question of who should actually do it, should it be done internally by an issues management department or as the trend is these days, by external specialists.

Another interesting question that came to mind when conducting the study concerned the strategic decision making process involved when choosing a response strategy to emerging issues. The literature clearly advocates for early intervention (the basic notion of issues management), but is it always the best choice? In relation to Letigen where the easy choice to resolve the issue in the early stages of its development would be to withdraw the product before both the Nycomed and Letigen received too much negative publicity. This raises more questions, who should decide – the product managers who in most companies are measured on hard figures? Also, when should an actual decision be made to solve an issue by changing the operations of a company, e.g. to withdraw a product? As soon as the issue is identified as having a high potential for threat or just before the issue enter the crisis phase?

Returning to the analysis framework again the final question that came to my mind when investigating the Letigen case, going through the four stages, was that it would be interesting to test and develop the framework further. An implementation or integration of more advanced forecasting techniques could strengthen the model further when dealing issues.

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